NHS

National Institute for
Clinical Excellence

Compilation

Summary of Guidance issued to the NHS in England and Wales

Issue 7

October 2003

NHS

National Institute for Clinical Excellence

ERRATUM

There is an error on pages 62 and 63 of Compilation issue 7.
NICE has not yet issued guidance on coil embolisation of ruptured intracranial aneurysms and the statements on this procedure should be disregarded.

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Compilation

Summary of Guidance issued to the NHS in England and Wales

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The Guidance in this document is written in the following context

This Guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgment. This Guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Acknowledgements

The development of NICE guidance relies on the time and commitment of those with whom the Institute works.

The Institute wishes to acknowledge the contribution of the members of the Appraisal Committee, the Guidelines Advisory Committee, the Partners Council, the academic teams, the national patient/carer organisations and individual manufacturers.

In addition, the Institute acknowledges the support, help, advice and commitment of a wide range of health professionals and their representative groups, including the Royal Colleges, numerous professional associations and societies and of course the wider NHS.

Introduction

The National Institute for Clinical Excellence (the Institute) is part of the NHS. It is a Special Health Authority and it provides guidance for the NHS and patients on medicines, medical equipment and clinical procedures based on evidence of both clinical and cost effectiveness.

The Institute has been described as a virtual network. It has 60 full time employees and works with patient/carer organisations, NHS R&D manufacturers, doctors, nurses, pharmacists, academics and other health professionals in England and Wales to prepare its guidance.

Full details on the Institute and its work are available on the NICE web site (www.nice.org.uk).

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How to use this document

- **Classification:** The Institute's guidance to the NHS has been categorised under the following headings:

  Section headings:
  Behavioural
  Cancer
  Cardiovascular
  Central nervous system
  Dental, oral and facial
  Ear, nose and throat
  Endocrine and metabolic
  Eye
  Gastrointestinal
  Gynaecology, pregnancy and birth
  Infections and infectious diseases
  Injuries and accidents
  Mental health
  Musculo-skeletal
  Nutritional disorders and weight control
  Renal and urinary
  Respiratory
  Skin disorders and wounds
  Miscellaneous

- **Index:** There is an alphabetical index at the back of this book.

- The Institute produces a range of guideance and when cross referenced with the work programme from which the guidance was produced will provide clarity as to the production method used.

  Clinical Guidelines: The Institute's work programme consists of two types of clinical guidelines; those termed 'inherited' and those termed 'new commissions'. Inherited guidelines means that they were commissioned before the Institute was formed in April 1999. Their development closely followed the brief that was agreed at the time of commissioning. It has not been possible to subject them to the full guideline development process that the Institute has adopted for its new commissions, however the guidelines have been reviewed by the Institute's Guidelines Advisory Committee (Appendix C). The Guidelines Advisory Committee was replaced on 1st April 2003 by a number of Independent Guideline Review Panels.

Technology Appraisals: The technology appraisals in this compilation contain only section 1 of the full guidance that is circulated to the NHS in England and Wales.

Section 1 constitutes the Institute's guidance. The remainder of the full guidance contains information on clinical need, evidence, implications for the NHS, further research, implementation, clinical audit advice and sources of evidence.

Interventional Procedures: The interventional procedures in this compilation contain only section 1 of the full guidance that is circulated to the NHS in England and Wales.

Section 1 constitutes the Institute's guidance. The remainder of the full guidance contains information on the procedure and sources of evidence.

Obtaining further information

Further information on the Institute and its work, including the full guidance and the evidence base are available from the Institute's web site (www.nice.org.uk). All documents can be ordered from the NHS Response Line. See Appendix H for further details.

Behavioural

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TECHNOLOGY APPRAISAL

Methylphenidate for Attention Deficit Hyperactivity Disorder (ADHD)

Issue date – October 2000 **Review date** – August 2003

Methylphenidate is recommended for use as part of a comprehensive treatment programme for children with a diagnosis of Severe Attention Deficit / Hyperactivity Disorder (ADHD). 'Severe ADHD' is broadly similar to a diagnosis of Hyperkinetic Disorder (HKD), although in some cases treatment may be appropriate for children and adolescents who do not fit the diagnostic criteria for HKD but are experiencing severe problems due to inattention or hyperactivity/impulsiveness.

Methylphenidate is not currently licensed for children under the age of six or for children with marked anxiety, agitation or tension; symptoms or family history of tics or Tourette's syndrome; hyperthyroidism; severe angina or cardiac arrhythmia; glaucoma; or thyrotoxicosis. Caution is required in the prescribing of methylphenidate for children and young people with epilepsy, psychotic disorders, or a history of drug or alcohol dependence.

Diagnosis should be based on a timely, comprehensive assessment conducted by a child/adolescent psychiatrist or a paediatrician with expertise in ADHD. It should also involve children, parents and carers and the child's school, and take into account cultural factors in the child's environment. Multidisciplinary assessment, which may include educational or clinical psychologists and social workers, is advisable for children who present with indications of significant co-morbidity.

Treatment with methylphenidate should only be initiated by child and adolescent psychiatrists or paediatricians with expertise in ADHD, but continued prescribing and monitoring may be performed by general practitioners, under shared care arrangements with specialists.

Careful titration is required to determine the optimal dose level and timing. The drug should be discontinued if improvement of symptoms is not observed after appropriate dose adjustment.

A comprehensive treatment programme should involve advice and support to parents and teachers, and could, but does not need to, include specific psychological treatment (such as behavioural therapy). While this wider service is desirable, any shortfall in its provision should not be used as a reason for delaying the appropriate use of medication.

Children on methylphenidate therapy should receive regular monitoring. When improvement has occurred and the child's condition is stable, treatment can be discontinued at intervals, under careful specialist supervision, in order to assess both the child's progress and the need for continuation of therapy.

This guidance relates only to children and adolescents with ADHD.

TECHNOLOGY APPRAISAL

Nicotine replacement therapy (NRT) and bupropion for smoking cessation

Issue date – March 2002 **Review date** – April 2005

Nicotine replacement therapy (NRT) and bupropion are recommended for smokers who have expressed a desire to quit smoking.

NRT or bupropion should normally only be prescribed as part of an abstinent-contingent treatment (ACT), in which the smoker makes a commitment to stop smoking on or before a particular date (target stop date). Smokers should be offered advice and encouragement to aid their attempt to quit. Ideally, initial prescription of NRT or bupropion should be sufficient to last only until 2 weeks after the target stop date. Normally, this will be after 2 weeks of NRT therapy, and 3–4 weeks for bupropion, to allow for the different methods of administration and mode of action. Second prescriptions should be given only to people who have demonstrated that their quit attempt is continuing on re-assessment.

It is recommended that smokers who are under the age of 18 years, who are pregnant or breastfeeding, or who have unstable cardiovascular disorders, should discuss the use of NRT with a relevant health-care professional before it is prescribed.

Bupropion is not recommended for smokers under the age of 18 years, as its safety and efficacy have not been evaluated for this group. Women who are pregnant or breastfeeding should not use bupropion.

If a smoker's attempt to quit is unsuccessful with treatment using either NRT or bupropion, the NHS should normally fund no further attempts within 6 months. However, if external factors interfere with an individual's initial attempt to stop smoking, it may be reasonable to try again sooner.

There is currently insufficient evidence to recommend the use of an NRT and bupropion in combination.

In deciding which of the available therapies to use and in which order they should be prescribed, practitioners should take into account:

- intention and motivation to quit, and likelihood of compliance
- the availability of counselling or support
- previous usage of smoking cessation aids
- contraindications and potential for adverse effects
- personal preferences of the smoker.

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[illegible]

Capecitabine and tegafur with uracil for metastatic colorectal cancer

Issue date – May 2003 **Review date** – January 2006

Oral therapy with either capecitabine or tegafur with uracil (in combination with folinic acid) is recommended as an option for the first-line treatment of metastatic colorectal cancer.

The choice of regimen (intravenous fluorouracil/folinic acid [5-FU/FA] or one of the oral therapies) should be made jointly by the individual and the clinician(s) responsible for treatment. The decision should be made after an informed discussion between the clinician(s) and the patient; this discussion should take into account contraindications and the side-effect profile of the agents as well as the clinical condition and preferences of the individual.

The use of capecitabine or tegafur with uracil to treat metastatic colorectal cancer should be supervised by oncologists who specialise in colorectal cancer.

[illegible]

Capecitabine for the treatment of locally advanced or metastatic breast cancer

Issue date – May 2003 **Review date** – January 2006

In the treatment of locally advanced or metastatic breast cancer, capecitabine in combination with docetaxel is recommended in preference to single-agent docetaxel in people for whom anthracycline-containing regimens are unsuitable or have failed.

Capecitabine monotherapy is recommended as an option for people with locally advanced or metastatic breast cancer who have not previously received capecitabine in combination therapy and for whom anthracycline and taxane-containing regimens have failed or further anthracycline therapy is contraindicated.

The decision regarding treatment should be made jointly by the individual and the clinician(s) responsible for treatment. The decision should be made after an informed discussion between the clinician(s) and the patient; this discussion should take into account contraindications and the side-effect profile of the agents, alternative treatments for locally advanced or metastatic breast cancer, and the clinical condition and preferences of the individual.

The use of capecitabine to treat locally advanced or metastatic breast cancer should be supervised by oncologists who specialise in breast cancer.

TECHNOLOGY APPRAISAL

Docetaxel, paclitaxel, gemcitabine and vinorelbine for non-small cell lung cancer

Issue date – June 2001 **Review date** – May 2003

Chemotherapy for non-small cell lung cancer (NSCLC) should be considered as an option in patients who are unsuitable for, or considered unlikely to respond to an attempt at curative treatment.

Gemcitabine, paclitaxel, and vinorelbine should each be considered as part of first-line chemotherapy options for advanced (stage III and IV) NSCLC patients. Combination of these three agents individually with platinum-based chemotherapy, where tolerated, is likely to be the most effective approach.

Docetaxel monotherapy should be considered where second line treatment is appropriate for patients with locally advanced or metastatic NSCLC when relapse has occurred after prior chemotherapy.

Chemotherapy regimens should be administered under the supervision of appropriately trained health professionals experienced in the use of cancer chemotherapeutic agents and should be accompanied by best supportive care. Informed decisions regarding appropriate chemotherapy should take account of side effect profiles, use of concurrent radiotherapy, performance status of the individual being treated and patient and carer preferences. Total cost differences between the various chemotherapy regimens should also be taken into account.

Fludarabine for chronic B-cell lymphocytic leukaemia

Issue date – September 2001 **Review date** – August 2004

Oral fludarabine is recommended as second line therapy for B-cell chronic lymphocytic leukaemia (CLL) for patients who have either failed, or are intolerant of, first line chemotherapy, and who would otherwise have received combination chemotherapy of either:

- cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP)
- cyclophosphamide, doxorubicin and prednisolone (CAP) or
- cyclophosphamide, vincristine and prednisolone (CVP).

The oral formulation of fludarabine is preferred to the intravenous formulation on the basis of more favourable cost effectiveness. Intravenous fludarabine should only be used when oral fludarabine is contra-indicated.

Gemcitabine for pancreatic cancer

Issue date – May 2001 **Review date** – April 2004

Gemcitabine may be considered as a treatment option for patients with advanced or metastatic adenocarcinoma of the pancreas and a Karnofsky performance score of 50 or more, where first line chemotherapy is to be used.

Gemcitabine is not recommended for patients who are suitable for potentially curative surgery, or patients with a Karnofsky score of less than 50.

There is insufficient evidence to support the use of gemcitabine as a second line treatment in patients with pancreatic adenocarcinoma.

TECHNOLOGY APPRAISAL

Imatinib for chronic myeloid leukaemia

Issue date – September 2002 **Review date** – September 2003

Imatinib is recommended as a treatment option for the management of Philadelphia-chromosome-positive chronic myeloid leukaemia (CML) in chronic phase in adults who are intolerant of interferon-alpha (IFN-∝) therapy or in whom IFN-∝ is deemed to have failed to control the disease.

IFN-∝ failure is defined as either:

- failure to achieve complete haematological response after 3 months of IFN-∝ treatment as monotherapy or in combination with hydroxyurea, or
- failure to achieve major cytogenetic response after 1 year of IFN-∝ treatment despite haematological response.

IFN-∝ intolerance is defined as the presence of documented Grade 3 non-haematological toxicity, persisting for more than 2 weeks, in a patient receiving a regimen that contains IFN-∝.

Imatinib is recommended as an option for the treatment of adults with Philadelphia-chromosome-positive CML in accelerated phase or blast crisis provided they have not received imatinib treatment at an earlier stage.

TECHNOLOGY APPRAISAL

Irinotecan, oxaliplatin and raltitrexed for advanced colorectal cancer

Issue date – March 2002 **Review date** – April 2005

On the balance of clinical and cost-effectiveness, neither irinotecan nor oxaliplatin in combination with 5-fluorouracil and folinic acid (5FU/FA) are recommended for routine first-line therapy for advanced colorectal cancer.

Oxaliplatin should be considered for use as first-line therapy, in combination with 5FU/FA, in advanced colorectal cancer in patients with metastases that are confined solely to the liver and may become resectable ('down staged') following treatment.

Irinotecan monotherapy is recommended in patients who have failed an established 5-fluorouracil containing treatment regimen.

On the balance of evidence relating to its clinical and cost effectiveness, raltitrexed is not recommended for the treatment of advanced colorectal cancer. Its use for this patient group should be confined to appropriately designed clinical studies.

It is likely that patients currently receiving irinotecan or oxaliplatin in combination with 5FU/FA or raltitrexed could suffer loss of well being if their treatment is discontinued at a time they did not anticipate. Because of this, patients and their consultants may wish to continue therapy until they consider it is appropriate to stop.

Laparoscopic radical prostatectomy

Issue date – October 2003

Current evidence on the safety and efficacy of laparoscopic radical prostatectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake laparoscopic radical prostatectomy should inform the clinical governance leads in their Trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.

Patients should be informed that radical prostatectomy by any technique can control local symptoms of prostate cancer, but that it can also have significant complications. They should be informed that there is no reliable evidence showing whether or not radical prostatectomy improves survival. (Some studies compare the results of laparoscopic radical prostatectomy with those from other treatment carried out some years ago. The stage of disease may be different in patients in the earlier studies, making the comparison invalid. See also NICE Cancer Service Guidance, *Improving Outcomes in Urological Cancer*, available from www.nice.org.uk.).

Laparoscopic radical prostatectomy requires specialist training before it is undertaken. The British Association of Urological Surgeons has agreed to produce training standards.

TECHNOLOGY APPRAISAL

Laparoscopic surgery for colorectal cancer

Issue date – December 2000 **Review date** – August 2003

For colorectal cancer, open rather than laparoscopic resection should be the preferred surgical procedure.

Laparoscopic surgery should only be undertaken for colorectal cancer as part of a randomised controlled clinical trial.

TECHNOLOGY APPRAISAL

Liquid based cytology for cervical screening

Issue date – June 2000 **Review date** – May 2003

Research evidence suggests that Liquid Based Cytology (LBC) could provide significant and important benefits. However, the quality of the evidence is variable and some areas of uncertainty remain. Although there is insufficient evidence to justify the nationwide introduction of LBC technology at this time, it is likely that LBC will have the effect of reducing the number of false negative test results as well as the number of unsatisfactory specimens. In addition, it may decrease the time needed for examination of specimens by cytologists.

In order to establish its contribution, a programme of pilot implementation projects of LBC should be undertaken, accompanied by a full review of the results at each stage. This should be done before consideration is given to the general introduction of this technology nationally. These projects should evaluate all the effects, costs and practical implications of introducing LBC technology into the cervical screening programme, including the following:

- the effect on test results (proportions of tests classified as inadequate, negative, borderline/mild dyskaryosis, moderate dyskaryosis, severe dyskaryosis or worse) and the consequent need for repeat screening, recall in less than three years and additional diagnostic investigations;
- the extent to which productivity improvements in cytology laboratories are realised in routine practice, the acceptability of LBC to laboratory staff and their needs for training, and the identification of quality assurance guidance prior to full implementation;
- the impact in the primary care setting with regard to the training of screening personnel, avoidance of repeat visits and ease of implementation;
- the logistical implications of implementing LBC, including transport of specimens, storage, waste disposal and laboratory throughput.

The proposed pilots should be designed to complement the Scottish LBC demonstration projects and trials of other cervical screening technologies, such as screening for Human Papillomavirus. The Institute recommends initial implementation on a regional scale to ensure proper testing of the effects of LBC, but the design of the pilot studies needs careful consideration in order to provide adequate and robust data. The Institute also recommends that the NHS Research and Development Programme should be asked to advise on the number and design of the pilot studies.

[illegible]

Paclitaxel in the treatment of ovarian cancer

Issue date – January 2003 **Review date** – July 2003

This guidance replaces Technology Appraisal Guidance No 3 published in May 2000. The review and re-appraisal of the use of paclitaxel in the treatment of ovarian cancer has resulted in a change in the guidance. Specifically there has been:

- *a change in recommendations on the alternative treatments offered for first-line therapy*

- *an emphasis that women should be involved in making choices about their treatment*
- *clarification of the distinction between re-challenge and second-line treatment.*

There has been no significant change in the guidance on the use of paclitaxel in the second-line (or subsequent) treatment.

It is recommended that paclitaxel in combination with a platinum based compound or platinum-based therapy alone (cisplatin or carboplatin) are offered as alternatives for first-line chemotherapy (usually following surgery) in the treatment of ovarian cancer.

The choice of treatment for first-line chemotherapy for ovarian cancer should be made after discussion between the responsible clinician and the patient about the risks and benefits of the options available. In choosing between treatment with a platinum-based compound alone or paclitaxel in combination with a platinum-based compound, this discussion should cover the side-effect profiles of the alternative therapies, the stage of the woman's disease, the extent of surgical treatment of the tumour, and disease-related performance status.

When relapse occurs after an initial (or subsequent) course of first-line chemotherapy, additional courses of treatment with the chosen chemotherapy regimen (re-challenge therapy) should be considered if the initial (or previous) response has been adequate in extent and duration. Once the tumour fails to respond adequately to the chosen first-line regimen, different treatment options should be considered as part of second-line therapy (see below).

Paclitaxel is not recommended as second-line (or subsequent) therapy in women with ovarian cancer who have received the drug as part of their first-line treatment. For women who have not received paclitaxel as part of first-line treatment, it should be considered as one option alongside other drugs licensed for second-line treatment of ovarian cancer.

Only oncologists specialising in ovarian cancer should supervise the provision of chemotherapy in ovarian cancer.

TECHNOLOGY APPRAISAL

Pegylated liposomal doxorubicin hydrochloride for the treatment of advanced ovarian cancer

Issue date – June 2002 **Review date** – April 2003

Pegylated liposomal doxorubicin hydrochloride (PLDH) is recommended as one option for the second-line (or subsequent) treatment of women with advanced ovarian cancer that is initially resistant or refractory to first-line platinum-based combination therapy or has become resistant after successive cycles of platinum-based combination therapy.

Only oncologists specialising in ovarian cancer should supervise the provision of PLDH treatment in ovarian cancer.

The use by oncologists of PLDH to treat advanced ovarian cancer should be accompanied by ongoing monitoring of its use, with careful documentation of indications for treatment, clinical outcomes and adverse effects.

PLDH is not recommended for patients with condition-related poor performance status (e.g. ECOG 3 or worse) or sub-acute or established bowel obstruction, or for patients who have previously not responded to PLDH.

Treatment response should include an assessment of the patient, and be monitored by appropriate tumour markers (e.g. CA-125) and/or appropriate radiological techniques. Patients with evidence of disease progression based on clinical assessment, augmented where appropriate with evidence from serological tests or radiological imaging, should stop treatment. Deteriorating performance status should also prompt consideration of treatment withdrawal.

INTERVENTIONAL PROCEDURE

Radiofrequency ablation of hepatocellular carcinoma

Issue date – July 2003

Current evidence of the safety and efficacy of radiofrequency ablation (RFA) for hepatocellular carcinoma appears adequate to support use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.

It is recommended that:

- patient selection should be carried out by a multidisciplinary team that includes a hepatobiliary surgeon
- the procedure should be monitored by CT or ultrasound.

[redacted]

Rituximab for aggressive non Hodgkin's lymphoma [redacted]

Issue date – September 2003 **Review date** – August 2006

Rituximab is recommended for use in combination with a regimen of cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) for the first-line treatment of people with CD20-positive diffuse large-B-cell lymphoma at clinical stage II, III or IV*. Rituximab is not recommended for use when CHOP is contraindicated.

The clinical and cost effectiveness of rituximab in patients with localised disease (Stage I) has not been established. It is recommended that rituximab be used in these circumstances only as part of ongoing or new clinical studies.

A specialist in the treatment of lymphomas should supervise the use of rituximab in combination with CHOP for the treatment of diffuse large-B-cell lymphoma.

* DLBCL typically presents as a nodal or extranodal mass, sometimes with systemic symptoms, such as sweats, fatigue and fever. In about 40% of people these lymphomas appear in areas outside lymph nodes, including the digestive tract, skin, bone, thyroid and testes. Surgery is typically carried out for diagnostic purposes; once DLBCL is identified, it is staged to find out how far the disease has spread:

Stage I Involvement of a single lymph-node region [I] or localised involvement of a single extralymphatic organ or site (IE)

Stage II	Involvement of two or more lymph-node regions on the same side of the diaphragm [II] or localised involvement of a single associated extralymphatic organ or site and its regional lymph nodes with or without other lymph node regions on the same side of the diaphragm (IIE)
Stage III	Involvement of lymph-node regions on both sides of the diaphragm [III] that may also be accompanied by localised involvement of an extralymphatic organ or site (IIIE), by involvement of the spleen (IIIS), or both (IIIS+E)
Stage IV	Disseminated (multifocal) involvement of one or more extralymphatic sites with or without associated lymph node involvement or isolated extralymphatic organ involvement with distant (non-regional) nodal involvement.

[illegible]

Rituximab for recurrent or refractory stage III or IV follicular non-Hodgkin's lymphoma

Issue date – March 2002 **Review date** – April 2005

The use of rituximab for third-line or subsequent-line, but not 'last-line', treatment of patients with recurrent or refractory Stage III or IV follicular lymphoma is not recommended.

For last-line treatment, rituximab is recommended only in the context of a prospective case series. All patients for whom alternative therapies have been exhausted (that is, those who are either chemo-resistant or chemo-intolerant) would be appropriate for inclusion in the case series on the basis that data are systematically collected to allow aggregation and analysis at a national level. The Institute's recommendations for data to be recorded for this case series are set out in the full guidance.

TECHNOLOGY APPRAISAL

Taxanes for breast cancer (review)

Issue date – September 2001 **Review date** – August 2003

This replaces the previous guidance on taxanes for breast cancer in June 2000.

The use of docetaxel in combination with an anthracycline in first-line treatment of advanced breast cancer is not currently recommended. As paclitaxel is not licensed for first-line use with anthracycline its use has not been considered in this indication.

Docetaxel and paclitaxel are recommended as an option for the treatment of advanced breast cancer where initial cytotoxic chemotherapy (including an anthracycline) has failed or is inappropriate.

The taxanes are not currently licensed in the UK for adjuvant treatment of early breast cancer therefore their use in this indication should be limited to randomised clinical trials.

TECHNOLOGY APPRAISAL

Temozolomide for malignant glioma (brain cancer)

Issue date – April 2001 **Review date** – March 2004

Patients with recurrent malignant glioma (brain cancer) who have failed first-line chemotherapy treatment with other agents (either because of lack of efficacy or because of side effects) may be considered for treatment with temozolomide. Such patients must have a histologically proven malignant glioma (WHO grades III and IV, or transformed grade II) at first relapse, recurrence or progression (as assessed by imaging), Karnofsky performance status greater than or equal to 70 and a projected life expectancy of 12 weeks or more, at initiation of temozolomide treatment.

Temozolomide is not recommended for first-line chemotherapy treatment for patients with malignant glioma who have failed primary therapy (surgery and/or radiotherapy), except in the context of a randomised controlled trial against a standard-treatment comparator.

As temozolomide is not currently licensed for adjuvant chemotherapy treatment of malignant glioma, its use in this indication has not been considered in this appraisal.

[illegible]

Topotecan for advanced ovarian cancer

Issue date – August 2001 **Review date** – June 2002

It is recommended that topotecan should be considered as one option for the second-line (or subsequent) treatment of women with advanced ovarian cancer where the disease is initially resistant or refractory to first-line platinum based combination therapy or has become resistant after successive courses of platinum based combination therapy.

Use of topotecan is not recommended in patients with poor performance status (ECOG 3 or worse), sub-acute or established bowel obstruction, or after previous exposure to topotecan or another drug in the same class.

Only oncologists specialising in the chemotherapy of ovarian cancer should undertake supervision of topotecan treatment in advanced ovarian cancer.

The use by oncologists of topotecan in this indication should be accompanied by ongoing audit of its use, with careful documentation of indications for treatment, clinical outcomes and adverse effects.

Treatment response should be monitored by appropriate tumour markers (e.g. CA-125) and/or appropriate radiological techniques. Patients with serological or radiological evidence of disease progression should stop treatment. Deteriorating performance status should also prompt consideration of treatment withdrawal.

Trastuzumab for advanced breast cancer

Issue date – March 2002 **Review date** – April 2005

Trastuzumab in combination with paclitaxel (combination trastuzumab is currently only licensed for use with paclitaxel) is recommended as an option for people with tumours expressing human epidermal growth factor receptor 2 (HER2) scored at levels of 3+ who have not received chemotherapy for metastatic breast cancer and in whom anthracycline treatment is inappropriate.

Trastuzumab monotherapy is recommended as an option for people with tumours expressing HER2 scored at levels of 3+ who have received at least two chemotherapy regimens for metastatic breast cancer. Prior chemotherapy must have included at least an anthracycline and a taxane where these treatments are appropriate. It should also have included hormonal therapy in suitable oestrogen receptor positive patients.

HER2 levels should be scored using validated immunohistochemical techniques and in accordance with published guidelines. Laboratories offering tissue sample immunocytochemical or other predictive tests for therapy response should use validated standardised assay methods and participate in and demonstrate satisfactory performance in a recognised external quality assurance scheme.

Vinorelbine for the treatment of advanced breast cancer

Issue date – December 2002 **Review date** – June 2005

Vinorelbine monotherapy is not recommended as a first-line treatment for advanced breast cancer.

Vinorelbine monotherapy is recommended as one option for second line or later therapy for the treatment of advanced breast cancer when anthracycline-based regimens have failed or are unsuitable. The choice of appropriate second-line or later treatment for advanced breast cancer should be made jointly by the patient and the clinician responsible for treatment after an informed discussion of the relative benefits of the available drugs and their side-effect profiles.

The present state of evidence does not allow the Institute to recommend the routine use of vinorelbine combination therapies.

Cardiovascular

Clinical Guidelines

Chronic heart failure – Management of chronic heart failure in adults in primary and secondary care 32 NEW

MI prophylaxis – drug treatment, cardiac rehabilitation and dietary manipulation 68

Interventional Procedures

Coil embolisation of ruptured intracranial aneurysms 62 NEW

Radiofrequency ablation of varicose veins 73 NEW

Stent–graft placement in abdominal aortic aneurysm 73 NEW

Technology Appraisals

Coronary artery stents for ischaemic heart disease 63

Early thrombolysis drugs for acute myocardial infarction 64

Glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes (review) 65

Implantable cardioverter defibrillators for arrhythmias 66

Chronic heart failure – Management of chronic heart failure in adults in primary and secondary care

Issue date – July 2003 **Review date** – July 2007

The grading scheme and hierarchy of evidence used in this guideline are shown in the table below.

EVIDENCE LEVELS

Table 1 Levels of evidence

Level	Type of evidence
Ia	Evidence obtained from systematic review of meta-analysis of randomized controlled trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomization
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies
IV	Evidence from expert committee reports or opinions and/or clinical experience of respected authorities
DS	Evidence from diagnostic studies
NICE	Evidence from NICE guidelines or health technology appraisal programme

DERIVATION AND GRADING OF TABLES

Table 2 Grading of recommendations

Grade	Evidence
Ⓐ	At least one randomized controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia and Ib)

Table 2 Grading of recommendations (continued)

Grade	Evidence
Ⓑ	Well-conducted clinical studies but no randomized clinical trials on the topic of recommendation (evidence levels IIa, IIb, III)
Ⓒ	Expert committee reports or opinions and/or clinical experience of respected authorities. This grading indicates that directly applicable clinical studies or good quality are absent (evidence level IV)
GPP	Recommended good practice based on the clinical experience of the Guideline Development Group
DS	Evidence from diagnostic studies
NICE	Evidence from NICE guidelines or health technology appraisal programme

Adapted from: National Institute for Clinical Excellence (2001). *The Guideline Development Process – Information for National Collaborating Centres and Guideline Development Groups*. London: National Institute for Clinical Excellence. Available from www.nice.org.uk.

Heart failure is a complex syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the heart to function as a pump to support a physiological circulation. The syndrome of heart failure is characterised by symptoms such as breathlessness and fatigue, and signs such as fluid retention. This guideline offers best practice advice on the care of adult patients (aged 18 years or older) who have symptoms or a diagnosis of chronic heart failure. It aims to define the most effective combination of symptoms, signs and investigations required to establish a diagnosis of heart failure, and those which will influence therapy or provide important prognostic information. It also gives guidance on the treatment, monitoring and support of patients with heart failure.

KEY RECOMMENDATIONS

The following recommendations have been identified as priorities for implementation.

Diagnosis

The basis for historical diagnoses of heart failure should be reviewed, and only patients whose diagnosis is confirmed should be managed in accordance with this guideline.

Doppler 2D echocardiographic examination should be performed to exclude important valve disease, assess the systolic (and diastolic) function of the (left) ventricle and detect intracardiac shunts.

Treatment

All patients with heart failure due to left ventricular systolic dysfunction should be considered for treatment with an ACE inhibitor.

Beta blockers licensed for use in heart failure should be initiated in patients with heart failure due to left ventricular systolic dysfunction after diuretic and ACE inhibitor therapy (regardless of whether or not symptoms persist).

Monitoring

All patients with chronic heart failure require monitoring. This monitoring should include:

- a clinical assessment of functional capacity, fluid status, cardiac rhythm, and cognitive and nutritional status
- a review of medication, including need for changes and possible side effects
- serum urea, electrolytes and creatinine.

Discharge

Patients with heart failure should generally be discharged from hospital only when their clinical condition is stable and the management plan is optimised.

The primary care team, patient and carer must be aware of the management plan.

Supporting patients and carers

Management of heart failure should be seen as a shared responsibility between patient and healthcare professional.

GUIDANCE

Diagnosing heart failure

The full evaluation of heart failure is more than stating whether the syndrome is present or not; it requires consideration of the underlying abnormality of the heart, the severity of the syndrome, the aetiology, precipitating and exacerbating factors, identification of concomitant disease relevant to the management, and an estimation of prognosis. It is important to exclude other conditions that may masquerade as heart failure (see Table 3 below). The recommendations for diagnosing heart failure are summarised in an algorithm (Figure 1) below.

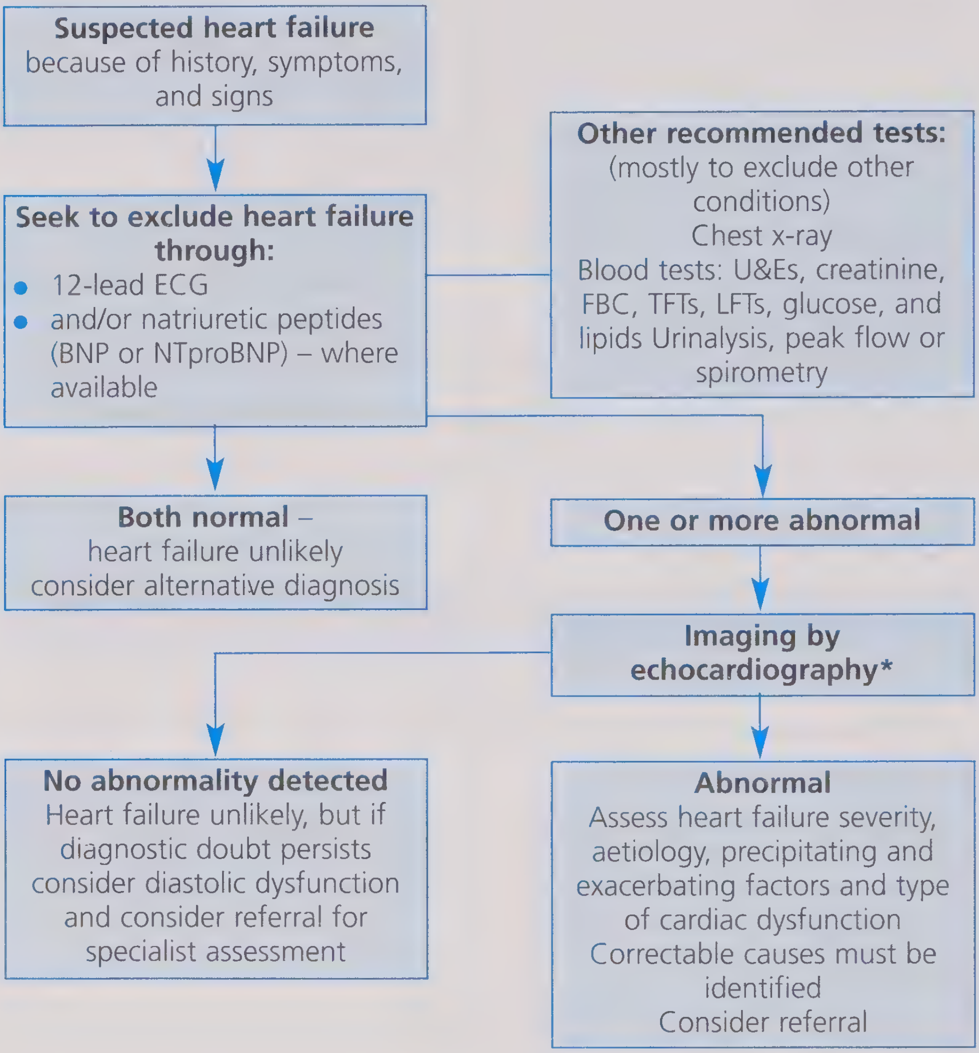
Table 3 Conditions presenting with similar symptoms

Other conditions that may present with similar symptoms	
Obesity	Hypoalbuminaemia
Chest disease – including lung, diaphragm or chest wall	Intrinsic renal or hepatic disease
Venous insufficiency in lower limbs	Pulmonary embolic disease
Drug-induced ankle swelling (e.g. dihydropyridine calcium channel blockers)	Depression and/or anxiety disorders
Drug-induced fluid retention (e.g. NSAIDs)	Severe anaemia or thyroid disease
Bilateral renal artery stenosis	

CARDIAC ASSESSMENT

- Take a careful and detailed history, and perform a clinical examination. These should be combined with tests to confirm the presence of heart failure and make a complete diagnosis. GPP

Figure 1 Algorithm summarising recommendations for the diagnosis of heart failure


Suspected heart failure
because of history, symptoms, and signs
Seek to exclude heart failure through:
● 12-lead ECG
● and/or natriuretic peptides (BNP or NTproBNP) – where available
Other recommended tests:
(mostly to exclude other conditions)
Chest x-ray
Blood tests: U&Es, creatinine, FBC, TFTs, LFTs, glucose, and lipids Urinalysis, peak flow or spirometry
Both normal –
heart failure unlikely
consider alternative diagnosis
One or more abnormal
Imaging by echocardiography*
No abnormality detected
Heart failure unlikely, but if diagnostic doubt persists consider diastolic dysfunction and consider referral for specialist assessment
Abnormal
Assess heart failure severity, aetiology, precipitating and exacerbating factors and type of cardiac dysfunction
Correctable causes must be identified
Consider referral

* Alternative methods of imaging the heart should be considered when a poor image is produced by transthoracic Doppler 2D echocardiography – alternatives include transoesophageal Doppler 2D echocardiography, radionuclide imaging or cardiac magnetic resonance imaging

Key:

BNP	B-type natriuretic peptide
ECG	Electrocardiogram
FBC	Full blood count
LFTs	Liver function tests
NTproBNP	N-terminal pro-B-type natriuretic peptide
TFTs	Thyroid function tests
U&Es	Urea and electrolytes

- Healthcare professionals should seek to exclude a diagnosis of heart failure through the following investigations:
  - 12-lead ECG
  - and/or natriuretic peptides (BNP or NTproBNP) – where available.

If one or both are abnormal, a diagnosis of heart failure cannot be excluded and transthoracic Doppler 2D echocardiography should be performed because it consolidates the diagnosis and provides information on the underlying functional abnormality of the heart.Ⓑ

- Efforts should be made to exclude other disorders that may present in a similar manner. GPP
- To evaluate possible aggravating factors and/or alternative diagnoses the following tests are recommended. GPP
  - Chest X-ray
  - Blood tests:
    - ○ biochemical profile including electrolytes, urea and creatinine
    - ○ full blood count
    - ○ thyroid function tests
    - ○ liver function tests
    - ○ fasting lipids
    - ○ fasting glucose
  - Urinalysis
  - Peak flow or spirometry.
- Transthoracic Doppler 2D echocardiographic examination should be performed to exclude important valve disease, assess the systolic (and diastolic) function of the (left) ventricle, and detect intracardiac shunts. GPP
- Transthoracic Doppler 2D echocardiographic studies should be performed on high-resolution equipment, by experienced operators trained to the relevant professional standards. Need and demand for these studies should not compromise quality. GPP

- The reporting of echocardiography should be by those experienced in doing so. GPP
- Alternative methods of imaging the heart should be considered when a poor image is produced by echocardiography. Such methods may include radionuclide angiography, cardiac magnetic resonance imaging, or transoesophageal Doppler 2D echocardiography.Ⓑ

DIASTOLIC HEART FAILURE

- Where the diagnosis is unclear, or if a diagnosis of diastolic heart failure is being considered, the patient should be referred for more specialist assessment. GPP

REVIEW OF EXISTING DIAGNOSES

- The basis for historical diagnoses of heart failure should be reviewed, and only patients whose diagnosis is confirmed should be managed in accordance with this guideline. GPP
- If the diagnosis of heart failure is still suspected, but confirmation of the underlying cardiac abnormality has not occurred, then the patient should have appropriate further investigation. GPP

Treating heart failure

Treatments are available that can improve the life expectancy and quality of life of a person with heart failure. Treatment recommendations are given below, and include aspects of lifestyle, pharmacological therapy, and invasive procedures. It is also helpful to consider the need to keep patients fully informed about their condition and the treatment options, and this is reflected in the recommendations.

LIFESTYLE

Exercise training and rehabilitation

- Patients with heart failure should be encouraged to adopt regular aerobic and/or resistive exercise. This may be more effective when part of an exercise programme or a programme of rehabilitation.Ⓑ

Smoking

- Patients must be strongly advised not to smoke. Referral to smoking cessation services should be considered. GPP

Alcohol

- Patients with alcohol-related heart failure should abstain from drinking alcohol. Ⓒ
- Healthcare professionals should discuss alcohol consumption with the patient and tailor their advice appropriately to the clinical circumstances. GPP

Sexual activity

- Healthcare professionals should be prepared to broach sensitive issues with patients, such as sexual activity, as these are unlikely to be raised by the patient. GPP

Vaccination

- Patients with heart failure should be offered an annual vaccination against influenza. GPP
- Patients with heart failure should be offered vaccination against pneumococcal disease (only required once). GPP

Air travel

- Air travel will be possible for the majority of patients with heart failure, depending on their clinical condition at the time of travel. GPP

Driving regulations

- Heavy Goods Vehicle and Public Service Vehicle licence: physicians should be up to date with the latest Driver and Vehicle Licensing Authority guidelines. Check the website for regular updates: www.dvla.gov.uk/ GPP

PHARMACOLOGICAL THERAPY FOR PATIENTS WITH HEART FAILURE DUE TO LEFT VENTRICULAR SYSTOLIC DYSFUNCTION.

Drug therapy is required for the vast majority of patients with heart failure. It is the responsibility of the individual prescriber to check the dosage of medication. This document should be read as a guide to treatment rather than being considered a protocol that must be followed prescriptively in all patients. Treatment should be tailored to the individual patient, with referral for more specialist advice being considered where appropriate.

Note that at the time of issue of this guideline, the following drugs in this guideline are unlicensed in the UK for the treatment of heart failure or its common signs or symptoms.

- angiotensin II receptor antagonists
- the positive inotropic agent dobutamine
- calcium channel blockers.

RECOMMENDATIONS ON SPECIFIC DRUGS

Recommendations for pharmacological therapy for patients with heart failure due to left ventricular systolic dysfunction are summarised in the algorithm in figure 2 below.

Diuretics

- Diuretics (see Table A at the end of this guidance) should be routinely used for the relief of congestive symptoms and fluid retention in patients with heart failure, and titrated (up and down) according to need following the initiation of subsequent heart failure therapies. Ⓒ

Angiotensin converting enzyme (ACE) inhibitors

- All patients with heart failure due to left ventricular systolic dysfunction should be considered for treatment with an ACE inhibitor (see Table B at the end of this guidance). Ⓐ
- ACE inhibitor therapy should be instituted in patients with heart failure due to left ventricular systolic dysfunction before beta-blockade is introduced. Ⓐ
- ACE inhibitor therapy should be initiated at the appropriate dose, and titrated upwards at short intervals (for example, every 2 weeks) until the optimal tolerated or target dose is achieved. GPP
- Blood biochemistry (urea, creatinine and electrolytes) should be measured after initiation and at each dose increment. GPP

Beta-blockers

- Beta-blockers licensed for use in heart failure should be initiated in patients with heart failure due to left ventricular systolic dysfunction after diuretic and ACE inhibitor therapy (regardless of whether or not symptoms persist). See Table C at the end of this guidance.Ⓐ

- Beta-blockade therapy for heart failure should be introduced in a 'start low, go slow' manner, with assessment of heart rate, blood pressure, and clinical status after each titration.Ⓒ
- Patients who develop heart failure due to left ventricular systolic dysfunction and who are already on treatment with a beta-blocker for a concomitant condition (for example, angina, hypertension) should continue with a beta-blocker – either their current beta-blocker or an alternative licensed for heart failure treatment. GPP

Aldosterone antagonists

- Patients with heart failure due to left ventricular systolic dysfunction who remain moderately to severely symptomatic despite optimal therapy (as outlined in the algorithm) should be prescribed spironolactone at a dose of 12.5 to 50 mg once per day (See Table D at the end of this guidance) – specialist advice should be sought.Ⓐ
- Patients with heart failure taking spironolactone should have blood potassium and creatinine levels monitored for signs of hyperkalaemia and/or deteriorating renal function – see 'Monitoring' below for further details. If hyperkalaemia is a problem then the dose of spironolactone should be halved and biochemistry rechecked. GPP

Digoxin

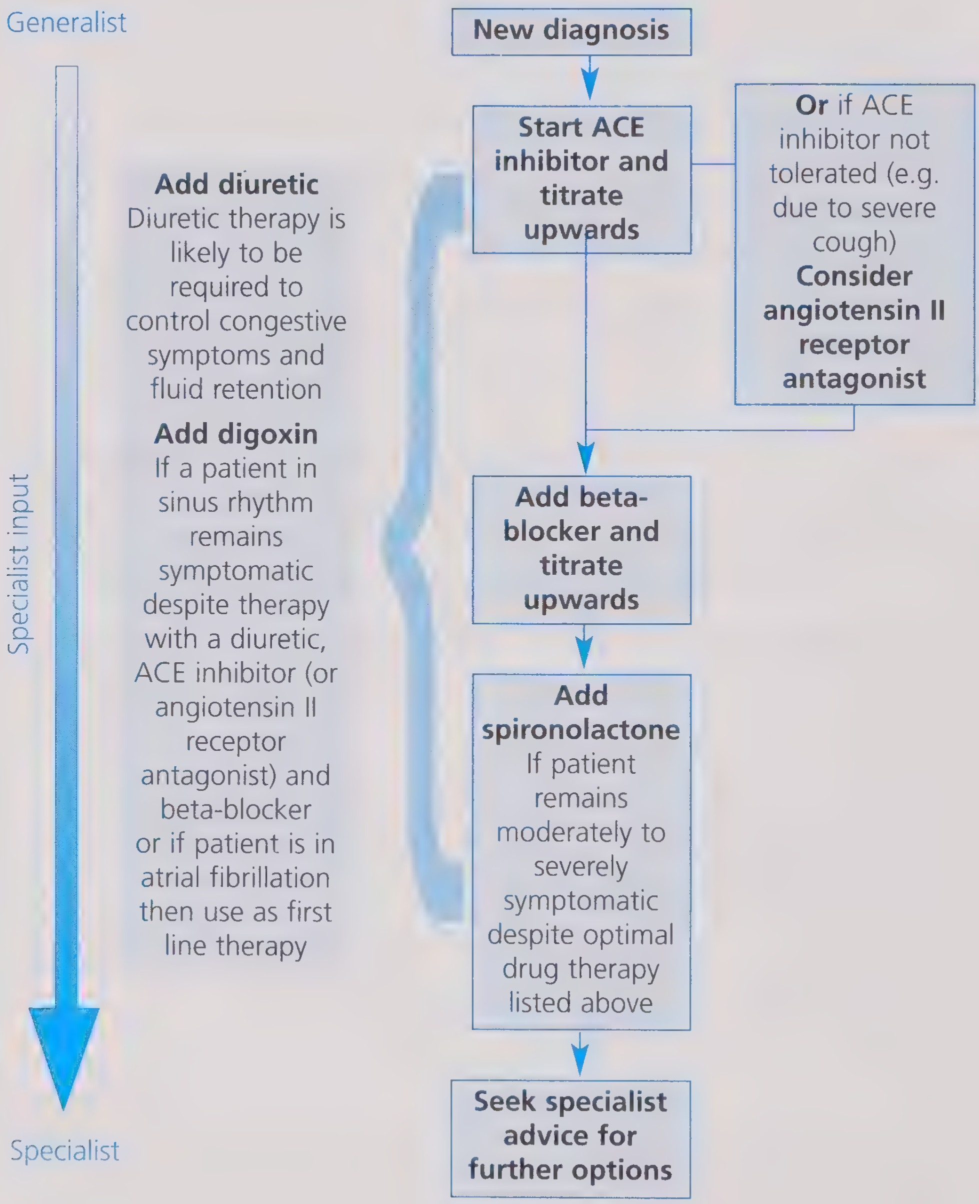
- Digoxin is recommended for:
  - worsening or severe heart failure due to left ventricular systolic dysfunction despite ACE inhibitor, beta-blocker and diuretic therapyⒶ
  - patients with atrial fibrillation and any degree of heart failure.Ⓒ

Figure 2 Algorithm for the pharmacological treatment of symptomatic heart failure due to left ventricular systolic dysfunction

Patients with symptomatic heart failure due to left ventricular systolic dysfunction should be treated with the following drugs (if tolerated and not contraindicated) and in the sequence indicated. The reader must refer to the text of the guideline for more detailed discussion and explanation.

Please note:

- Diuretic is first-line therapy when a patient presents with acute pulmonary oedema
- Please refer to Appendix Tables for starting doses of drugs
- The arrow on the left-hand margin indicates the increasing likelihood of the need for specialist input.



New diagnosis

Start ACE inhibitor and titrate upwards

Or if ACE inhibitor not tolerated (e.g. due to severe cough) **Consider angiotensin II receptor antagonist**

Add diuretic Diuretic therapy is likely to be required to control congestive symptoms and fluid retention

Add digoxin If a patient in sinus rhythm remains symptomatic despite therapy with a diuretic, ACE inhibitor (or angiotensin II receptor antagonist) and beta-blocker or if patient is in atrial fibrillation then use as first line therapy

Add beta-blocker and titrate upwards

Add spironolactone If patient remains moderately to severely symptomatic despite optimal drug therapy listed above

Seek specialist advice for further options

Angiotensin II receptor antagonists

- At the time of issue of this guideline, angiotensin II receptor antagonists (Table E at the end of this guidance) are not licensed in the UK for heart failure and studies are ongoing. However, angiotensin II receptor antagonists may provide an alternative to ACE inhibitors for patients intolerant of ACE inhibitors (for example, because of cough).Ⓐ
- The triple combination of ACE inhibitor, beta-blocker and angiotensin II receptor antagonist should be avoided, pending the results of further trials. GPP

Amiodarone

- The decision to prescribe amiodarone should be made in consultation with a specialist. GPP
- The need to continue the prescription should be reviewed regularly. GPP
- Patients taking amiodarone should have a routine 6-monthly clinical review, including liver and thyroid function test, and including a review of side effects. GPP

Anticoagulants

- Anticoagulation is indicated for patients with the combination of heart failure and atrial fibrillation (see also 'Recommendations for patients with heart failure and atrial fibrillation', below).Ⓐ
- In patients with heart failure in sinus rhythm, anticoagulation should be considered for those with a history of thromboembolism, left ventricular aneurysm, or intracardiac thrombus. GPP

Aspirin

- Aspirin (75–150 mg once daily) should be prescribed for patients with the combination of heart failure and atherosclerotic arterial disease (including coronary heart disease).Ⓑ

Statins (hydroxymethylglutaryl-coenzyme A reductase inhibitors)

- Patients with the combination of heart failure and known atherosclerotic vascular disease should receive statins only in accordance with current indications. Specific trials in this area are ongoing. GPP

Isosorbide/hydralazine combination (specialist initiation only)

- An isosorbide/hydralazine combination may be used in patients with heart failure who are intolerant of ACE inhibitors or angiotensin II receptor antagonists.Ⓐ

Inotropic agents (specialist use only)

- Intravenous inotropic agents (such as dobutamine, milrinone or enoximone) should only be considered for the short-term treatment of acute decompensation of chronic heart failure. This will require specialist advice.Ⓐ

Calcium channel blockers

- Amlodipine should be considered for the treatment of co-morbid hypertension and/or angina in patients with heart failure, but verapamil, diltiazem or short-acting dihydropyridine agents should be avoided.Ⓐ

MAJOR CO-MORBIDITIES THAT IMPACT ON THE PHARMACOLOGICAL MANAGEMENT OF HEART FAILURE

The presence of certain co-morbidities may affect the drugs that can be used for the treatment of heart failure, or increase the likelihood of side effects. The major co-morbidities that impact on the management of heart failure are summarised in Table F at the end of this guidance.

SIDE EFFECTS OF DRUGS COMMONLY USED IN THE TREATMENT OF HEART FAILURE

All drugs have side effects. See the Summary of Product Characteristics for individual drugs for details.

IMPROVING ADHERENCE TO PHARMACOLOGICAL THERAPY

- Dosing regimens should be kept as simple as possible, and the healthcare professional should ensure that the patient and carer are fully informed about their medication.Ⓑ

Invasive procedures

Although drug therapy is the mainstay of treatment of heart failure, some patients will also benefit from diagnostic or interventional invasive procedures. These procedures are normally organised by a specialist. This guideline can only give general advice, and specialist advice is strongly recommended where such procedures might be considered.

CORONARY REVASCULARISATION

- Coronary revascularisation should not be routinely considered in patients with heart failure due to systolic left ventricular impairment, unless they have refractory angina. Ⓒ

CARDIAC TRANSPLANTATION

- Specialist referral for transplantation should be considered in patients with severe refractory symptoms or refractory cardiogenic shock. Ⓒ

CARDIAC RESYNCHRONISATION THERAPY

- Resynchronisation therapy should be considered in selected patients with left ventricular systolic dysfunction (left ventricular ejection fraction ≤ 35%), drug refractory symptoms, and a QRS duration > 120 ms. The results of ongoing trials will help guide appropriate patient selection. Ⓐ

IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS (ICDS)

- Recommendation from *NICE Technology Appraisal Guidance No. 11*, Guidance on the use of implantable cardioverter defibrillators for arrhythmias (see *Implantable cardioverter defibrillators for arrhythmias* in this section). The use of implantable cardioverter defibrillators (ICDs) should be routinely considered for patients in the following categories: NICE 2000

1. Secondary prevention, that is for patients who present, in the absence of a treatable cause, with:
   - cardiac arrest due to either ventricular tachycardia (VT) or ventricular fibrillation
   - spontaneous sustained VT causing syncope or significant haemodynamic compromise
   - sustained VT without syncope/cardiac arrest, and who have an associated reduction in ejection fraction (less than 35%) but are no worse than Class III* of the New York Heart Association functional classification of heart failure.

2 'Primary prevention' for patients with:

- a history of previous myocardial infarction and all of the following:
  - i) non-sustained VT on Holter (24-hour ECG) monitoring
  - ii) inducible VT on electrophysiological testing
  - iii) left ventricular dysfunction with an ejection fraction less than 35% and no worse than Class III* of the New York Heart Association functional classification of heart failure.
- A familial cardiac condition with a high risk of sudden death, including long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome, arrhythmogenic right ventricular dysplasia and following repair of tetralogy of Fallot.

* Marked limitation of physical activity. Although patients are comfortable at rest, less than ordinary physical activity will lead to symptoms (symptomatically 'moderate' heart failure)

Oxygen therapy and continuous airway pressure

The evidence for oxygen therapy and continuous positive airway pressure was considered during development of this guideline, but it was not possible to make specific recommendations because of the small evidence base. For further details, see the full guideline (*Chronic Heart Failure: Management of Chronic Heart Failure in Adults in Primary and Secondary Care*, published by the National Collaborating Centre for Chronic Conditions; available on its website www.rcplondon.ac.uk/college/ceeu/ ncccc_index.htm).

Recommendations for treatment of heart failure not due to left ventricular systolic dysfunction

VALVE DISEASE

- Patients with heart failure due to valve disease should be referred for specialist assessment and advice regarding follow-up. Ⓒ
- ACE inhibitor therapy should not be initiated in a patient

with a clinical suspicion of haemodynamically significant valve disease, until the valve disease has been assessed by a specialist.Ⓒ

DIASTOLIC DYSFUNCTION

- The diagnosis and treatment of diastolic dysfunction should be made by a specialist, and other conditions that present in a similar way may need to be considered. Patients in whom this diagnosis has been made should usually be treated with a low to medium dose of loop diuretics (for example, less than 80 mg furosemide per day). Patients who do not respond to this treatment will require further specialist advice. GPP

OTHER CAUSES

The management of other causes of heart failure requires specialist input. This would include congenital heart disease, cardiomyopathies, and specific heart muscle disease such as amyloid.

Recommendations for patients with heart failure and atrial fibrillation

- For patients with heart failure and atrial fibrillation, specialist advice should be sought as to whether the aim is improvement of heart rate control or cardioversion (return to sinus rhythm).Ⓒ
- Anticoagulation is indicated for patients with heart failure and atrial fibrillation (see also 'anticoagulation', above).Ⓐ

Recommendations for different subgroups of patients with heart failure

AGE

- The management of heart failure should be determined by clinical criteria, irrespective of the age of the patient.Ⓐ
- Tolerance of drugs may be lower and side effects require closer and more frequent monitoring in older patients. GPP

GENDER

- The principles of pharmacological management of heart failure should be the same for men and women. GPP

- The potential teratogenic effects of drugs should be considered. GPP

PREGNANCY

- In women of reproductive age who have heart failure, contraception and pregnancy should be discussed. If pregnancy is being considered or occurs, specialist advice should be sought. Subsequently, specialist care should be shared between the cardiologist and obstetrician. GPP

ETHNICITY

- The principles of pharmacological management should be the same for all patients with heart failure, regardless of ethnicity. GPP

Monitoring

The clinical condition of a person with heart failure may fluctuate and repeated admission to hospital is common, particularly for patients with more severe heart failure. Monitoring of clinical status is necessary and will involve healthcare professionals in both primary and secondary care. Patients and their carers are playing an increasing role in monitoring, but this requires appropriate education and support.

CLINICAL REVIEW

- All patients with chronic heart failure require monitoring. This monitoring should include (see Table 4, below): GPP
  - clinical assessment of functional capacity, fluid status, cardiac rhythm (minimum of examining the pulse), cognitive status and nutritional status
  - a review of medication, including need for changes and possible side effects
  - serum urea, electrolytes and creatinine*.

  * This is a minimum. Patients with co-morbidities or co-prescribed medications will require further monitoring. Monitoring serum potassium is particularly important if a patient is taking digoxin or spironolactone.

Table 4 Assessments to be made at clinical review

Assessment of functional capacity	Chiefly from history, but more objectively by use of New York Heart Association class, specific quality-of-life questionnaires, 6-minute walk test, or maximal exercise test. Note: not all of these tests are likely to be necessary, or appropriate, at each assessment.
Assessment of fluid status	Chiefly by physical examination – changes in body weight, extent of jugular venous distension, lung crackles and hepatomegaly, extent of peripheral oedema, and lying and standing blood pressure (postural drop in blood pressure may indicate hypovolaemia)
Assessment of cardiac rhythm	Chiefly by clinical examination, but may require 12-lead electrocardiogram (ECG) or 24-hour electrocardiographic ('Holter') monitoring if suspicion of arrhythmia
Laboratory assessment	Checking of serum biochemistry (urea, electrolytes, creatinine) is essential, but other tests (such as thyroid function, haematology, liver function, level of anticoagulation) may also be required depending on the medication prescribed and co-morbidity

- More detailed monitoring will be required if the patient has significant co-morbidity or has deteriorated since the previous review. GPP
- The frequency of monitoring should depend on the clinical status and stability of the patient. The monitoring interval should be short (days to 2 weeks) if the clinical condition or medication has changed, but is required at least 6 monthly for stable patients with proven heart failure. GPP
- Patients who wish to be involved in monitoring of their condition should be provided with sufficient education and support from their healthcare professional to do this, with clear guidelines as to what to do in the event of deterioration. GPP

THERAPEUTIC DRUG MONITORING OF SERUM DIGOXIN CONCENTRATIONS

- Routine monitoring of serum digoxin concentrations is not recommended. A digoxin concentration measured within 8–12 hours of the last dose may be useful to confirm a clinical impression of toxicity or non-compliance. GPP
- The serum digoxin concentration should be interpreted in the clinical context as toxicity may occur even when the concentration is within the 'therapeutic range'. GPP

Referral and approach to care

The management of heart failure is likely to be shared between healthcare professionals in both primary and secondary care. Patients and their carers are increasingly involved in management decisions. Work with patient focus groups suggests that the major failings of management relate to poor communication between healthcare professionals, and between patients and the professionals caring for them. GPP

REFERRAL FOR MORE SPECIALIST ADVICE

- Patients with heart failure require specialist advice in the following situations. GPP
  - Heart failure due to valve disease, diastolic dysfunction or any other cause except left ventricular systolic dysfunction.
  - One or more of the co-morbidities outlined in Appendix Table F.
  - Angina, atrial fibrillation or other symptomatic arrhythmia.
  - Women who are planning a pregnancy or who are pregnant.
- The following situations also require referral.
  - Severe heart failure.
  - Heart failure that does not respond to treatment as discussed in this guideline and outlined in the algorithm.
  - Heart failure that can no longer be managed effectively in the home setting. GPP

DISCHARGE PLANNING

- Patients with heart failure should generally be discharged from hospital only when their clinical condition is stable and the management plan is optimised. Timing of discharge should take into account patient and carer wishes, and the level of care and support that can be provided in the community. GPP
- The primary care team, patient and carer must be aware of the management plan. GPP
- Clear instructions should be given as to how the patient/carer can access advice particularly in the high-risk period immediately following discharge. GPP

MULTIDISCIPLINARY TEAM APPROACH TO HEART FAILURE MANAGEMENT

- Heart failure care should be delivered by a multidisciplinary team with an integrated approach across the healthcare community. Ⓐ

NON-NHS AGENCIES

- Standard One of The Older People NSF states: Social care services will not use age in their eligibility criteria or policies to restrict access to available services. This applies to patients with heart failure. (See www.doh.gov.uk/nsf/olderpeople.htm) GPP
- Management plans for patients with heart failure should be discussed with non-NHS agencies where they are involved in or responsible for the care of a person with heart failure. GPP
- The principles of pharmacological management for a patient cared for in a non-NHS institution should be similar to those for any other patient with heart failure. GPP
- The education needs of non-NHS agency carers should be considered. GPP

Supporting patients and carers

Understanding the information needs of patients and carers is vital. Key issues identified by patient focus groups include the importance of honesty and accurate information, and the potential value of support groups. The recommendations below are based on earlier consensus guidelines produced by a Royal College of Physicians' working party.

COMMUNICATION

- Good communication between healthcare professionals and patients and carers is essential for the best management of heart failure. GPP
- Guidelines for good communication. Ⓒ
    - Listen to patients and respect their views and beliefs.
    - Give patients the information they ask for or need about their condition, its treatment and prognosis, in a way they can understand, including information about any serious side effects of drugs to be prescribed.
    - Provide the most important information first.
    - Explain how each item will affect patients personally.
    - Present information in separate categories.
    - Make advice specific, detailed and concrete.
    - Use words the patients will understand; confirm understanding by questions; define unfamiliar words; write down key words; draw diagrams and keep a copy in the medical notes.
    - Repeat the information using the same words each time.
    - Prepare material, written or taped, to back up handwritten notes.
    - Share information with patients' partners, close relatives or carers if they ask you to do so. When patients cannot indicate their consent for such sharing of information, it is advisable to share the information that those close to the patient need or want to know, except where you have reason to believe that the patient would object if able to do so.
- The content, style and timing of information provision should be tailored to the needs of the individual patient. Ⓒ
- Healthcare professionals should assess cognitive ability when sharing information. GPP
- Carers and relatives of patients who are cognitively impaired

should be made aware of treatment regimens for the patients they care for and be encouraged to identify any need for clinical support. GPP

- Management of heart failure should be seen as a shared responsibility between patient and healthcare professional. GPP
- Unless specifically excluded by the patient, carers and relatives should be involved in the management of the patient, particularly where the patient cannot look after him- or herself. GPP

PROGNOSIS

- Prognosis should be discussed with patients and carers in a sensitive, open and honest manner. GPP

SUPPORT GROUPS

- Healthcare professionals should be aware of local cardiac support networks and provide this information to patients and carers. GPP

Anxiety and depression

Depression tends to be more common in patients with heart failure than in the general population. Drug therapy with antidepressants may lead to complications such as fluid retention, hypotension and arrhythmias.

- The diagnosis of depression should be considered in all patients with heart failure.Ⓒ
- Where depression is likely to have been precipitated by heart failure symptoms then reassessment of psychological status should be undertaken once the physical condition has stabilised following treatment for heart failure. If the symptoms have improved no further specific treatment for depression is required.Ⓒ
- Where it is apparent that depression is co-existing with heart failure, then the patient should be treated for depression following the NICE guideline (Depression: the management of depression in primary and secondary care), scheduled for publication in February 2004.Ⓒ

- For patients with heart failure, the potential risks and benefits of drug therapies for depression should be considered carefully GPP
- Patients with heart failure should consult a healthcare professional before using over-the-counter therapies for depression such as St John's wort (*Hypericum perforatum*). Healthcare professionals should be aware of the potential interaction with prescribed medication, and always ask about self-medication, including the use of herbal products. GPP

End of life issues

There is substantial evidence for considerable unmet palliative needs of patients with heart failure and their informal carers. The main areas of need include symptom control, psychological and social support, planning for the future, and end of life care. GPP

- Issues of sudden death and living with uncertainty are pertinent to all patients with heart failure. The opportunity to discuss these issues should be available at all stages of care. GPP
- The palliative needs of patients and carers should be identified, assessed and managed at the earliest opportunity. GPP
- Patients with heart failure and their carers should have access to professionals with palliative care skills within the heart failure team. GPP

Table A Diuretics (oral): dosages and side effects

Drug	Initial dose (mg)	Maximum recommended daily dose (mg)
Loop diuretics		
Bumetanide	0·5–1·0	5–10
Furosemide	20–40	250–500
Torasemide	5–10	100–200

Table A Diuretics (oral): dosages and side effects (continued)

Drug	Initial dose (mg)		Maximum recommended daily dose (mg)	
*Thiazides**				
Bendroflumethiazide (previously called bendrofluazide)	2.5		5	
Indapamide	2.5		2.5	
Metolazone	2.5		10	
Potassium-sparing diuretic	*+ACEI*	*–ACEI*	*+ACEI*	*–ACEI*
Amiloride	2.5	5	20	40
Triamterene	25	50	100	200

For spironolactone, see Table D
ACEI, angiotensin converting enzyme inhibitor

*May be effective when added to loop diuretics when fluid retention is resistant, but can promote dramatic diuresis and disturbance in fluid balance and electrolytes. Patient must be closely monitored and specialist advice is required.

Table B Practical recommendations on the use of ACE inhibitors

Which ACE inhibitor and what dose?

Licensed ACEI	Starting dose (mg)	Target dose (mg)
Captopril	6.25 three times daily	50–100 three times daily
Cilazapril*	0.5 once daily	1–2.5 once daily
Enalapril	2.5 twice daily	10–20 twice daily
Fosinopril*	10 once daily	40 once daily
Lisinopril	2.5–5.0 once daily	30–35 once daily
Perindopril*	2.0 once daily	4 once daily
Quinapril*	2.5–5.0 once daily	10–20 once daily
Ramipril	2.5 once daily	5 twice daily or 10 once daily

*Target dose based on manufacturer's recommendation rather than large outcome study

How to use

- Start with a low dose (see above)
- Seek specialist advice where the patient is on a high dose (e.g. furosemide 80 mg) of a loop diuretic
- Double dose at not less than 2 weekly intervals
- Aim for target dose (see above) or, failing that, the highest tolerated dose
- Remember some ACE inhibitor is better than no ACE inhibitor
- Monitor blood electrolytes (in particular potassium), urea, creatinine, and blood pressure
- When to stop up-titration/down-titration; see ‘Problem solving’, overleaf

Advice to patient

- Explain expected benefits
- Treatment is given to improve symptoms, to prevent worsening of heart failure and to increase survival
- Symptoms improve within a few weeks to a few months
- Advise patients to report principal adverse effects (i.e. dizziness/symptomatic hypotension, cough)

Problem solving

- Asymptomatic low blood pressure does not usually require any change in therapy

Symptomatic hypotension

- If dizziness, light-headedness and/or confusion and a low blood pressure consider discontinuing nitrates, calcium channel blockers* and other vasodilators
- If no signs/symptoms of congestion consider reducing diuretic dose
- If these measures do not solve problem seek specialist advice

* Calcium channel blockers should be discontinued unless absolutely essential (e.g. for angina or hypertension).

Cough

- Cough is common in patients with chronic heart failure, many of whom have smoking-related lung disease
- Cough is also a symptom of pulmonary oedema which should be excluded when a new or worsening cough develops

- ACE inhibitor induced cough rarely requires treatment discontinuation
- If the patient develops a troublesome dry cough which interferes with sleep and is likely to be caused by an ACE inhibitor, consider substituting an angiotensin II receptor antagonist for the ACE inhibitor

Worsening renal function

- Some rise in urea, creatinine and K^+ is to be expected after initiation of an ACE inhibitor; if the increase is small and asymptomatic no action is necessary
- An increase in creatinine of up to 50% above baseline, or to 200 μmol/litre, whichever is the smaller, is acceptable
- An increase in K^+ to £ 5.9 mmol/litre is acceptable
- If urea, creatinine or K^+ do rise excessively consider stopping concomitant nephrotoxic drugs (e.g. NSAIDs), non-essential vasodilators (e.g. calcium antagonists, nitrates), K^+ supplements/ retaining agents (triamterene, amiloride) and, if no signs of congestion, reducing the dose of diuretic
- If greater rises in creatinine or K^+ than those outlined above persist despite adjustment of concomitant medications the dose of the ACE inhibitor should be halved and blood chemistry rechecked, if there is still an unsatisfactory response specialist advice should be sought
- If K^+ rises to ≥ 6.0 mmol/litre or creatinine increases by > 100% or to above 350 μmol/litre the dose of ACE inhibitor should be stopped and specialist advice sought
- Blood electrolytes should be monitored closely until K^+ and creatinine concentrations are stable

Note: it is very rarely necessary to stop an ACE inhibitor and clinical deterioration is likely if treatment is withdrawn; ideally, specialist advice should be sought before treatment discontinuation

Adapted from *European Journal of Heart Failure* 2001, 3, 495–502 (McMurray et al. Practical recommendations for the use of ACE inhibitors, beta-blockers and spironolactone in heart failure: putting guidelines into practice), copyright (2001), with permission from European Society of Cardiology.

Table C Practical recommendations on the use of beta-blockers

Which beta-blocker and what dose?

Only two beta-blockers are licensed for the treatment of heart failure in the UK at the time of issue of this guideline.

	Starting dose (mg)	Target dose (mg)
Bisoprolol	1.25 once daily	10 once daily
Carvedilol	3.125 twice daily	25–50 twice daily*

* Carvedilol: maximum dose 25 mg twice daily if severe heart failure. For patients with mild to moderate heart failure maximum dose 50 mg twice daily if weight more than 85 kg – otherwise maximum dose 25 mg twice daily

How to use

- Start with a low dose (see above)
- Double dose at not less than 2 weekly intervals
- Aim for target dose (see above) or, failing that, the highest tolerated dose
- Remember some beta-blocker is better than no beta-blocker
- Monitor heart rate, blood pressure, clinical status (symptoms, signs, especially signs of congestion, body weight)
- Check blood electrolytes, urea and creatinine 1–2 weeks after initiation and 1–2 weeks after final dose titration
- When to down-titrate/stop up-titration, see 'Problem solving', overleaf

Advice to patient

- Explain expected benefits
- Emphasise that treatment given as much to prevent worsening of heart failure as to improve symptoms; beta-blockers also increase survival
- If symptomatic improvement occurs, this may develop slowly (3–6 months or longer)
- Temporary symptomatic deterioration may occur (estimated 20–30% of cases) during initiation/up-titration phase
- Advise patient to report deterioration (see 'Problem solving') and that deterioration (tiredness, fatigue, breathlessness) can usually be easily managed by adjustment of other medication; patients should be advised not to stop beta-blocker therapy without consulting their physician

- Patients should be encouraged to weigh themselves daily (after waking, before dressing, after voiding, before eating) and to consult their doctor if they have persistent weight gain

Problem solving

Worsening symptoms/signs (e.g. increasing dyspnoea, fatigue, oedema, weight gain)

- If increasing congestion, double dose of diuretic and/or halve dose of beta-blocker (if increasing diuretic does not work)
- If marked fatigue (and/or bradycardia, see below) halve dose of beta-blocker (rarely necessary)
- Review patient in 1–2 weeks; if not improved seek specialist advice
- If serious deterioration halve dose of beta-blocker or stop this treatment (rarely necessary); seek specialist advice

Low heart rate

- If < 50 beats/min and worsening symptoms – halve dose beta-blocker or, if severe deterioration, stop beta-blocker (rarely necessary)
- Consider need to continue treatment with other drugs that slow the heart (e.g. digoxin, amiodarone, diltiazem) and discontinue if possible
- Arrange ECG to exclude heart block
- Seek specialist advice

Asymptomatic low blood pressure

- Does not usually require any change in therapy

Symptomatic hypotension

- If low blood pressure causes dizziness, light-headedness or confusion, consider discontinuing drugs such as nitrates, calcium channel blockers and other vasodilators
- If no signs/symptoms of congestion consider reducing diuretic dose
- If these measures do not solve problem seek specialist advice

Note: beta-blockers should not be stopped suddenly unless absolutely necessary (there is a risk of a 'rebound' increase in myocardial ischaemia/infarction and arrhythmias); ideally specialist advice should be sought before treatment discontinuation

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Adapted from *European Journal of Heart Failure* 2001, 3, 495–502 (McMurray et al. Practical recommendations for the use of ACE inhibitors, beta-blockers and spironolactone in heart failure: putting guidelines into practice), copyright (2001), with permission from European Society of Cardiology.

Table D Practical recommendations for the use of spironolactone

Which dose of spironolactone?

Dose (mg)
12.5–25 daily *

* 50 mg may be advised by a specialist if heart failure deteriorates and no problem with hyperkalaemia

How to use

- Start at 25 mg once daily
- Check blood chemistry at 1, 4, 8 and 12 weeks; 6, 9 and 12 months, 6 monthly thereafter
- If K^+ rises to between 5.5 and 5.9 mmol/litre or creatinine rises to 200 µmol/litre reduce dose to 25 mg on alternate days and monitor blood chemistry closely
- If K^+ rises to ≥ 6.0 mmol/litre or creatinine to > 200 µmol/litre stop spironolactone and seek specialist advice

Advice to patient

- Explain expected benefits
- Treatment is given to improve symptoms, prevent worsening of heart failure and to increase survival
- Symptom improvement occurs within a few weeks to a few months of starting treatment
- Avoid NSAIDs not prescribed by a physician (self-purchased ‘over the counter’ treatment e.g. ibuprofen)
- Temporarily stop spironolactone if diarrhoea and/or vomiting and contact physician

Problem solving

Worsening renal function/hyperkalaemia:

- See ‘How to use’
- Major concern is hyperkalaemia (≥ 6.0 mmol/litre) though this was uncommon in the RALES clinical trial; a potassium level at the higher

end of the normal range may be desirable in patients with heart failure, particularly if taking digoxin

- Some 'low salt' substitutes have a high K+ content
- Male patients may develop breast discomfort and/or gynaecomastia

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Table E Currently available angiotensin II receptor antagonists

Drug*	Daily dose (mg)
Candesartan	4–16
Eprosartan	400–800
Irbesartan	150–300
Losartan	50–100
Telmisartan	40–80
Valsartan	80–320

*None of these drugs is currently licensed for the treatment of heart failure in the UK

Table F Major co-morbidities that impact on the management of heart failure

Co-morbidity	Comments
COPD/asthma/ reversible airways disease	Beta-blockers are contraindicated in patients with reversible airways disease. The British National Formulary (45th edition, 2003) states 'Beta-blockers should be avoided in patients with a history of asthma or chronic obstructive airways disease; if there is no alternative, a cardioselective beta-blocker may be used with extreme caution under specialist supervision'.
Renal dysfunction	ACE inhibitors and angiotensin-II receptor antagonists (e.g. serum creatinine > 200 µmol/litre) may be contraindicated. Patient requires specialist assessment.
Anaemia	Anaemia is common in patients with moderate to severe heart failure and where due to the heart

Co-morbidity	Comments
	failure (and not other causes) treatment with erythropoeitin and iron therapy may improve symptoms and reduce the risk of hospitalisation for worsening heart failure. The results of several large RCTs addressing this issue are awaited.
Thyroid disease	Severe thyroid dysfunction may cause or precipitate heart failure.
Peripheral vascular disease	Not an absolute contraindication to beta-blocker therapy. High index of suspicion for renal artery stenosis required.
Urinary frequency	Requires appropriate specialist referral. Alpha-blockers may cause hypotension or fluid retention, but are not absolutely contraindicated in patients with heart failure. Diuretics likely to be less well tolerated.
Gout	Avoid non-steroidal anti-inflammatory drugs. Gout can be exacerbated by diuretics and may have an atypical presentation in patients with heart failure. Colchicine may be useful for the treatment of an acute attack of gout. Allopurinol may be useful at reducing the risk of furtherattacks of gout, but should not be started at the time of an acute episode of gout.

INTERVENTIONAL PROCEDURES

Coil embolisation of ruptured intracranial aneurysms

NOTE

This guidance relates to ruptured intracranial aneurysms only. Separate guidance will be published in the future on coil embolisation for unruptured aneurysms.

Current evidence on the safety and efficacy of coil embolisation of ruptured intracranial aneurysms appears adequate to support use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.

Patients with subarachnoid haemorrhage should have rapid access to appropriate specialist care. Clear arrangements should be in place for the involvement of different clinical disciplines in treatment and follow-up.

TECHNOLOGY APPRAISAL

Coronary artery stents for ischaemic heart disease

Issue date – May 2000 **Review date** – April 2003

For patients with either stable or unstable angina, or acute myocardial infarction (MI) and where percutaneous coronary intervention (PCI) is the clinically appropriate procedure, stents should be used routinely.

Where it is considered clinically appropriate to undertake either PCI or coronary artery bypass grafting (CABG), the availability of stents should push the balance of clinical decision-making towards PCI.

Arteries with a diameter of less than 2.5mm and greater than 3.5 mm should only normally be stented in the setting of a so-called 'bail out' procedure (i.e. when acute closure of the vessel occurs following PCI) or if there has been a sub-optimal result following ballooning alone or as part of properly conducted trials. These criteria do not apply to saphenous vein grafts (SVG). The Institute is aware that new evidence on stenting in arteries with a diameter less than 2.5 mm is likely to become available soon. If necessary, this guidance will be amended to take account of the fully reported results.

This guidance specifically relates to the present clinical indications for PCI and excludes conditions (such as many cases of stable angina) which are currently adequately managed with standard drug therapy.

TECHNOLOGY APPRAISAL

Early thrombolysis drugs for acute myocardial infarction

Issue date – October 2002 **Review date** – October 2005

NOTE

This guidance provides recommendations on the selection of thrombolytic drugs in patients with acute myocardial infarction (AMI). Recommendations are made in relation to the use of the drugs in hospital and pre-hospital settings. The guidance does not compare hospital and pre-hospital models of delivering thrombolysis.

It is recommended that, in hospital, the choice of thrombolytic drug (alteplase, reteplase, streptokinase or tenecteplase) should take account of:

- the likely balance of benefit and harm (for example, stroke) to which each of the thrombolytic agents would expose the individual patient
- current UK clinical practice, in which it is accepted that patients who have previously received streptokinase should not be treated with it again
- the hospital's arrangements for reducing delays in the administration of thrombolysis.

Where pre-hospital delivery of thrombolytic drugs is considered a beneficial approach as part of an emergency-care pathway for AMI (for example, because of population geography or the accessibility of acute hospital facilities), the practicalities of administering thrombolytic drugs in pre-hospital settings mean that the bolus drugs (reteplase or tenecteplase) are recommended as the preferred option.

TECHNOLOGY APPRAISAL

Glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes (review)

Issue date – September 2002 **Review date** – July 2005

This replaces the previous guidance on glycoprotein IIb/IIIa inhibitors issued in September 2000

NOTE

The review and re-appraisal of the glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes (ACS) has resulted in a revision of the definition of high-risk patients for the use of these agents in initial medical management of ACS, and a clarification of their use as an adjunct to percutaneous coronary interventions (PCI).

Glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitors should be considered part of the management pathway for unstable angina or non-ST-segment-elevation myocardial infarction (NSTEMI). This management pathway also includes other pharmacological interventions and, where appropriate, early coronary angiography with a view to revascularisation either by percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG).

The intravenous use of a small-molecule glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitor (eptifibatide or tirofiban), in addition to aspirin and unfractionated heparin, is recommended as part of the initial medical management of patients with unstable angina or NSTEMI who are at high risk of subsequent myocardial infarction (MI) or death.

Whilst it is recognised that early angiography is desirable for high-risk patients, in situations where PCI does not occur or is not immediately available, initial medical management with GP IIb/IIIa inhibitors is still recommended.

It is recommended that in determining who is at high risk, clinicians should take into account combinations of risk factors such as: clinical history, including age, previous MI, and previous PCI or CABG; clinical signs, including continuing pain despite initial treatment; and clinical investigations, such as

ECG changes (particularly dynamic or unstable patterns indicating myocardial ischaemia), haemodynamic changes and raised cardiac troponin levels.

Cardiac troponin testing is useful for diagnosing acute coronary syndromes and in risk stratification. However, it is recommended that in patients considered to be at high risk, treatment with a small-molecule GP IIb/IIIa inhibitor is initiated as soon as high-risk status is determined even though this may be before the result of a troponin test is known.

If PCI is indicated as part of the early management of unstable angina or NSTEMI, but it is delayed beyond the initial medical management phase, then the use of a GP IIb/IIIa inhibitor is recommended as an adjunct to the PCI. (Currently only abciximab is licensed as an adjunct to PCI.)

It is recommended that a GP IIb/IIIa inhibitor is considered as an adjunct to PCI for all patients with diabetes undergoing elective PCI, and for those patients undergoing complex procedures (for example, multi-vessel PCI, insertion of multiple stents, vein graft PCI or PCI for bifurcation lesions); currently only abciximab is licensed as an adjunct to PCI. In procedurally uncomplicated, elective PCI, where the risk of adverse sequelae is low, use of a GP IIb/IIIa inhibitor is not recommended unless unexpected immediate complications occur.

GP IIb/IIIa inhibitors are not currently licensed in the UK for use as an adjunct to thrombolytic therapy in ST-segment-elevation MI.

[illegible]

Implantable cardioverter defibrillators for arrhythmias

Issue date – September 2000 **Review date** – September 2003

The use of implantable cardioverter defibrillators (ICDs) should be routinely considered for patients in the following categories:

1 ‘Secondary prevention’ i.e. for patients who present, in the absence of a treatable cause, with:

- Cardiac arrest due to either ventricular tachycardia (VT) or ventricular fibrillation (VF).
- Spontaneous sustained VT causing syncope or significant haemodynamic compromise.
- Sustained VT without syncope/cardiac arrest, and who have an associated reduction in ejection fraction (less than 35%) but are no worse than class 3 of the New York Heart Association functional classification of heart failure.

2 'Primary prevention' for patients with:

- a history of previous myocardial infarction (MI) and all of the following:
  - non sustained VT on Holter (24 hour ECG) monitoring
  - inducible VT on electrophysiological testing
  - left ventricular dysfunction with an ejection fraction (EF) less than 35% and no worse than class 3 of the New York Heart Association functional classification of heart failure.
- a familial cardiac condition with a high risk of sudden death, including long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome, arrhythmogenic right ventricular dysplasia (ARVD) and following repair of Tetralogy of Fallot.

The use of implantable cardioverter defibrillators should not be routinely considered for patients in the following categories:

- Those with spontaneous sustained VT associated with minimal symptoms and good cardiac function (EF> 35%).
- Those who present with syncope of unknown cause (with no previous history of myocardial infarction) and who have inducible VT on electrophysiological testing (EPS) in the presence of normal cardiac function (EF>35%).

At this stage, the Institute considers that the evidence for patients with syncope of unknown origin, with haemodynamically significant sustained VT or VF induced at

EPS and in the presence of impaired cardiac function (i.e. ejection fraction (EF) <35%) is insufficient to recommend the use of ICDs.

[illegible]

MI prophylaxis – drug treatment, cardiac rehabilitation and dietary manipulation

Issue date – April 2001 **Review date** – April 2003

EVIDENCE

The recommendations in this guideline are graded according to the system set out below.

Ⓐ directly based on category I evidence (meta-analysis of randomised controlled trials or at least one randomised controlled trial)

Ⓑ directly based on category II evidence (at least one controlled study without randomisation or one other type of quasi-experimental study) or extrapolated recommendation from category I evidence

Ⓒ directly based on category III evidence (non-experimental descriptive studies) or extrapolated recommendation from category I or II evidence

Ⓓ directly based on category IV evidence (expert committee reports or opinions and/or clinical experience of respected authorities) or extrapolated recommendation from category I, II or III evidence

This guideline makes recommendations for patients who have survived a myocardial infarction and has the aim of decreasing subsequent premature mortality.

Recommendations for drug treatment are made assuming that clinicians will take account of both patient tolerability and compliance, and the indications, contra-indications and cautions as listed in the British National Formulary (BNF) or Summary of Product Characteristics.

Within three of the drug groups discussed in this guideline (beta-blockers, ACE inhibitors, statins) not all medicines have a license for the indications discussed in the guideline.

In reaching treatment decisions, clinicians will want to share the information in this guideline with patients so that they can be informed about and involved in decision making about their care.

GUIDANCE

Drug treatment

PATIENTS WITH PRIOR MYOCARDIAL INFARCTION WHO DO NOT HAVE HEART FAILURE

Which drugs?
All patients should be offered long term treatment firstly with a beta-blocker and an antiplatelet drug (aspirin), and then with a statin and an ACE inhibitor. This sequencing of initiation reflects the evidence from trials and estimates of cost-effectiveness Ⓐ. Not all ACE inhibitors or statins have a license for this indication.

The precise lower limit of the level of cholesterol that should be treated is unclear. Across the statin trials considered, the lower limit of the range of cholesterol values defining entry into the trials varied; one large trial enrolled patients with serum cholesterols down to 4 mmol/l. License indications currently suggest a lower limit of 4.8 mmol/l or 5.5 mmol/l depending on the drug used.Ⓓ

Beta-blockers and ACE inhibitors will also be considered for the management of symptoms (e.g. in stable angina) or risk factors (e.g. hypertension).Ⓓ

Calcium channel blockers, nitrates, and potassium channel activators have no effect on premature mortality making their role the management of symptoms and risk factors (principally hypertension) Ⓐ. They should therefore only be used in those patients who are intolerant of beta-blockers and ACE inhibitors Ⓓ. Given their effect on non-fatal myocardial infarction, verapamil or diltiazem should then be considered initially Ⓑ Subsequent necessary treatment with other calcium channel blockers, nitrates or potassium channel activators is then appropriate.Ⓓ

When to start drug treatment

The recommended starting points for drug treatments are based on the initiation points in the clinical trials.

Beta-blockers, antiplatelet drugs (aspirin) and ACE inhibitors should be initiated whilst patients are in hospital as there is evidence to support benefit following early initiation. If this does not happen then primary care clinicians should initiate them as soon after discharge as possible.Ⓐ

Although there is no evidence of the long-term benefit from the use of statins initiated prior to 12 weeks post-infarct, many patients will have been taking statins prior to admission or will have them initiated in hospital. All patients discharged from hospital who are not already taking a statin should be assessed and have treatment initiated 12 weeks after a myocardial infarction.Ⓐ

Monitoring treatment

Patients being considered for treatment with a statin should have an initial serum cholesterol measurement both to exclude familial lipid disorders and to identify those patients with a serum cholesterol level that does not need treating. Once these have been excluded, further measurement allows an assessment of response to treatment and informs the assessment of compliance with treatment. The frequency of such monitoring is unclear, however the National Service Framework for Coronary Heart Disease suggests annually.Ⓓ

Patients being considered for treatment with ACE inhibitors should have their renal function checked prior to initiation and after each significant dose increase.Ⓓ

Continuation of treatment

Based on the evidence from the trials, treatment should continue long term.Ⓓ

The treatment durations, for which there is at least one trial that provides direct support are three and a half years for antiplatelet drugs (aspirin), four years for beta-blockers and

ACE inhibitors and six years for statins. In the absence of a clear reason to stop treatment it seems reasonable to continue treatment indefinitely.Ⓓ

PATIENTS WITH PRIOR MYOCARDIAL INFARCTION WHO HAVE DIABETES

There is evidence that intensive insulin therapy initiated soon after admission for acute myocardial infarction reduces mortality Ⓑ. To achieve the benefits demonstrated in the single trial in this area involves 4 daily insulin injections continuing for at least three months.Ⓑ

PATIENTS WITH PRIOR MYOCARDIAL INFARCTION AND HEART FAILURE

Patients with prior myocardial infarction and heart failure are a relatively ill group of patients and care is required when initiating drug treatments.Ⓓ

All patients should be offered long term treatment with an ACE inhibitor and then a beta-blocker (not all beta-blockers have a license for this indication). In addition they should be treated with an antiplatelet drug (aspirin). Patients who have moderate or severe heart failure (New York Heart Association [NYHA] grade 3 or 4) should be treated with spironolactone. All of these treatments are cost effective.Ⓐ

Patients are likely to continue to need symptomatic treatment with a loop diuretic Ⓓ. In patients with mild symptoms of heart failure (NYHA grade 1 or 2) it is unclear whether spironolactone decreases premature mortality. It may represent a reasonable choice of adjuvant symptomatic therapy.Ⓓ

As patients with heart failure were almost always excluded from trials there is no evidence on which to recommend the use of statins in such patients. Statin use will be influenced by clinical and practical considerations, such as whether patients were treated with them prior to developing heart failure.Ⓓ

When to start drug treatment

The recommended starting points for drug treatments are based on the initiation points in the trials.

ACE inhibitors and antiplatelet drugs (aspirin) should be initiated whilst patients are in hospital as there is evidence to support benefit following early initiation. If this does not happen then primary care clinicians should initiate them as soon after discharge as possible.Ⓐ

Beta-blockers can be initiated at any point. Treatment should start with low doses and should be slowly increased, for example at fortnightly intervals, over a period of up to 12 weeks.Ⓐ

Given the limited experience initiating beta-blockers it is currently unclear whether this can be done safely in primary care. Whilst the BNF recommends hospital supervision it seems possible that there are a group of patients with heart failure for whom general practitioners (based on their knowledge of the patient's clinical condition) may feel able to initiate treatment in primary care. Unfortunately the characteristics of this patient group are not currently clear. Discussion at a local level may inform appropriate methods of treatment initiation.Ⓓ

Spironolactone can be initiated at any point. In patients with moderate to severe symptoms of heart failure (NYHA grade 3 or 4), given the time involved in achieving full dosages of beta-blockers, it seems reasonable to consider initiating spironolactone before beta-blockers.Ⓓ

Monitoring treatment

Patients being considered for treatment with ACE inhibitors should have their renal function checked prior to initiation and after each significant dose increase.Ⓓ

Patients being treated with spironolactone should have their serum potassium monitored.Ⓓ

Continuation of treatment

Based on the evidence from the trials, treatment should continue long term Ⓓ. The treatment durations, for which there is at least one trial that provides direct support, are three and a half years for ACE inhibitors, two and a half years for beta-blockers and two years for spironolactone. In the absence of a clear reason to stop treatment it seems reasonable to continue treatment indefinitely.Ⓓ

Non drug treatment

REHABILITATION

Patients should be offered enrolment in a rehabilitation programme that has a prominent exercise component within it.Ⓐ Although many of the trials imposed upper age limits for recruitment, the guideline development group felt that in a service setting it was more appropriate to be guided by functional ability and patient preference.Ⓓ

DIET

Given the nature of the available evidence of the effectiveness of dietary manipulation as a strategy for secondary prophylaxis it is not possible to recommend specific dietary manipulation.Ⓑ
Interventional procedure

INTERVENTIONAL PROCEDURE

Radiofrequency ablation of varicose veins

Issue date – September 2003

Current evidence on the safety and efficacy of radiofrequency ablation of varicose veins appears adequate to support the use of this procedure as an alternative to saphenofemoral ligation and stripping, provided that the normal arrangements are in place for consent, audit and clinical governance.

[illegible]

Stent–graft placement in abdominal aortic aneurysm

Issue date – September 2003

Current evidence on the safety and efficacy of stent–graft placement in abdominal aortic aneurysm does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake stent–graft placement in abdominal aortic aneurysms should inform the clinical governance leads in their trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty.

It is recommended that all patients who have the procedure should either be treated as part of the EndoVascular Aneurysm Repair (EVAR) trials or be entered onto one of the existing registries.

Central nervous system

Technology Appraisals

Beta interferon and glatiramer acetate for multiple sclerosis 76

Donepezil, rivastigmine and galantamine for Alzheimer's disease 76

Riluzole (Rilutek) for Motor Neurone Disease 78

TECHNOLOGY APPRAISAL

Beta interferon and glatiramer acetate for multiple sclerosis

Issue date – January 2002 **Review date** – November 2004

On the balance of their clinical and cost effectiveness neither beta interferon nor glatiramer acetate is recommended for the treatment of multiple sclerosis (MS) in the NHS in England and Wales.

It is likely that patients currently receiving beta interferon or glatiramer acetate for MS, whether as routine therapy or part of a clinical trial, could suffer loss of well being if their treatment is discontinued at a time they did not anticipate. Because of this, all NHS patients who are on therapy at the date of publication of this Guidance should have the option to continue treatment until they and their consultant consider it is appropriate to stop, having regard to the criteria established for withdrawal from treatment in the Guidelines of the Association of British Neurologists published in January 2001. This also applies to all participating patients at the conclusion of a clinical trial (irrespective as to whether they had received placebo or active drug) and women whose therapy has been interrupted by pregnancy.

The Department of Health and the National Assembly for Wales were asked to consider a strategy for acquiring any or all of the medicines appraised for this guidance in a manner that could be considered to be cost effective.

Note: There is now a national risk sharing scheme in place.

TECHNOLOGY APPRAISAL

Donepezil, rivastigmine and galantamine for Alzheimer's disease

Issue date – January 2001 **Review date** – December 2003

The three drugs donepezil, rivastigmine and galantamine should be made available in the NHS as one component of the management of those people with mild and moderate Alzheimer's disease (AD) whose mini mental state examination

(MMSE) score is above 12 points. Mild AD is usually associated with an MMSE of 21 to 26. Moderate AD is usually associated with an MMSE of 10 to 20. Severe AD is usually associated with an MMSE of less than 10. The clinical definition of AD severity must also take account of functional disability and social handicaps. These drugs should be made available under the following conditions:

- Diagnosis that the form of dementia is AD must be made in a specialist clinic according to standard diagnostic criteria.
- Assessment in a specialist clinic, including tests of cognitive, global and behavioural functioning and of activities of daily living, should be made before the drug is prescribed.
- Clinicians should also exercise judgement about the likelihood of compliance; in general, a carer or care-worker who is in sufficient contact with the patient to ensure compliance should be a minimum requirement.
- Only specialists (including old age psychiatrists, neurologists, and care of the elderly physicians) should initiate treatment. Carers' views of the patient's condition at baseline and follow-up should be sought. If general practitioners are to take over prescribing, it is recommended that they should do so under an agreed shared-care protocol with clear treatment end points.
- A further assessment should be made, usually two to four months after reaching maintenance dose of the drug. Following this assessment the drug should be continued only where there has been an improvement or no deterioration in MMSE score, together with evidence of global improvement on the basis of behavioural and/or functional assessment.
- Patients who continue on the drug should be reviewed by MMSE score and global, functional and behavioural assessment every 6 months. The drug should normally only be continued while their MMSE score remains above 12 points, and their global, functional and behavioural condition remains at a level where the drug is considered to be having a worthwhile effect. When the MMSE score falls below 12 points, patients should not normally be prescribed

any of these three drugs. Any review involving MMSE assessment should be undertaken by an appropriate specialist team, unless there are locally-agreed protocols for shared care.

The benefits of these three drugs for patients with other forms of dementia (e.g. dementia with Lewy Bodies) has not been assessed in this guidance.

TECHNOLOGY APPRAISAL

Riluzole (Rilutek) for Motor Neurone Disease

Issue date – January 2001 **Review date** – January 2004

Riluzole is recommended for the treatment of individuals with the amyotrophic lateral sclerosis (ALS) form of Motor Neurone Disease (MND).

Riluzole therapy should be initiated by a neurological specialist with expertise in the management of MND. Routine supervision of therapy should be managed by locally agreed shared care protocols undertaken by general practitioners.

Dental, oral and facial

Interventional Procedure

Stereotactic radiosurgery for trigeminal neuralgia using the gamma knife 80 NEW

Technology Appraisal

Wisdom teeth – appropriate removal 80

[illegible]

Stereotactic radiosurgery for trigeminal neuralgia using the gamma knife

Issue date – September 2003

Current evidence on the safety and efficacy of stereotactic radiosurgery for trigeminal neuralgia using the gamma knife does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake stereotactic radiosurgery for trigeminal neuralgia using the gamma knife should inform the clinical governance leads in their trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research.

This decision relates only to use of the gamma knife. It is noted that other forms of stereotactic radiation treatment exist.

[illegible]

Wisdom teeth – appropriate removal

Issue date – March 2000 **Review date** – March 2003

The routine practice of prophylactic removal of pathology-free impacted third molars should be discontinued in the NHS.

The standard routine programme of dental care by dental practitioners and/or paraprofessional staff, need be no different, in general, for pathology free impacted third molars (those requiring no additional investigations or procedures).

Surgical removal of impacted third molars should be limited to patients with evidence of pathology. Such pathology includes unrestorable caries, non-treatable pulpal and/or periapical pathology, cellulitis, abcess and osteomyelitis, internal/external resorption of the tooth or adjacent teeth, fracture of tooth, disease of follicle including cyst/tumour, tooth/teeth impeding surgery or reconstructive jaw surgery, and when a tooth is involved in or within the field of tumour resection.

Specific attention is drawn to plaque formation and pericoronitis. Plaque formation is a risk factor but is not in itself an indication for surgery. The degree to which the severity or recurrence rate of pericoronitis should influence the decision for surgical removal of a third molar remains unclear. The evidence suggests that a first episode of pericoronitis, unless particularly severe, should not be considered an indication for surgery. Second or subsequent episodes should be considered the appropriate indication for surgery.

Ear, nose and throat

Interventional Procedure

Coblation tonsillectomy 83 NEW

Technology Appraisal

Hearing aid technology 83

INTERVENTIONAL PROCEDURE

Coblation tonsillectomy

NEW

Issue date – September 2003

Current evidence on the safety and efficacy of coblation tonsillectomy appears adequate to support the use of this procedure, provided that the normal arrangements for consent, audit and clinical governance are in place.

Proper training in the performance of coblation tonsillectomy is required. At the Institute's request, the British Association of Otorhinolaryngologists, Head and Neck Surgeons is producing training standards for this procedure.

TECHNOLOGY APPRAISAL

Hearing aid technology

Issue date – July 2000 **Review date** – July 2002

The full range of analogue hearing aids in the current NHS range should be available at all NHS audiology centres. The device offered to an individual patient should be based on a careful matching of device capability to need and on patient choice and should include binaural fitting where indicated. The presumption should be that the more sophisticated analogue aids will confer more benefit than the basic linear aids. Patient choice should be enabled to take account of both function and design.

The NHS Purchasing and Supply Agency should review the existing NHS range of analogue aids against the full range of analogue aids currently available.

There is insufficient robust scientific evidence to support the nationwide introduction of digital hearing aids at present. Evidence regarding the benefits of digital devices as compared to the current NHS range and to more sophisticated analogue devices, is expected to be available after the completion of research projects currently being undertaken in the UK. Further evaluation of digital technology and its implementation will take place in a number of projects including the Modernising Hearing Aids First Wave Project (formerly known as 'Beacon

Sites') being established by the Department of Health in England.

Endocrine and metabolic

Clinical Guidelines

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TECHNOLOGY APPRAISAL

Continuous subcutaneous insulin infusion for diabetes

Issue date – February 2003 **Review date** – February 2006

Continuous subcutaneous insulin infusion (CSII or 'insulin pump therapy') is recommended as an option for people with type 1 diabetes provided that:

- multiple-dose insulin (MDI) therapy (including, where appropriate, the use of insulin glargine) has failed; and
- those receiving the treatment have the commitment and competence to use the therapy effectively.

People for whom MDI therapy has failed are considered to be those for whom it has been impossible to maintain a haemoglobin A_{1c} level no greater than 7.5% (or 6.5% in the presence of microalbuminuria or adverse features of the metabolic syndrome) without disabling hypoglycaemia occurring, despite a high level of self care of their diabetes. 'Disabling hypoglycaemia', for the purposes of this guidance, means the repeated and unpredictable occurrence of hypoglycaemia requiring third-party assistance that results in continuing anxiety about recurrence and is associated with significant adverse effect on quality of life.

CSII therapy should be initiated only by a trained specialist team, which should normally comprise a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietitian.

All individuals beginning CSII therapy should be provided with specific training in its use. Ongoing support from a specialist team should be available, particularly in the period immediately following the initiation of CSII. It is recommended that specialist teams should agree a common core of advice appropriate for CSII users.

The recommendations in this guidance are also applicable to children, adolescents, pre-pregnant and pregnant women for whom MDI therapy is deemed to have failed. Because of the risks of ketoacidosis to the fetus, pregnant or pre-pregnant women who switch to CSII therapy should do so only on the advice and under the care of a specialist team (defined above).

CSII therapy is not recommended for people with type 2 diabetes who require insulin therapy.

Established users of CSII therapy should have their insulin management reviewed by their specialist team so that a decision can be made about whether a trial of a switch to MDI incorporating insulin glargine would be appropriate.

TECHNOLOGY APPRAISAL

Glitazones for the treatment of type 2 diabetes

Issue date – August 2003 **Review date** – July 2006

This guidance replaces Technology Appraisal Guidance No. 9 issued in August 2000 and Technology Appraisal Guidance No. 21 issued in March 2001.

The review and re-appraisal of the use of glitazones in the treatment of type 2 diabetes has resulted in a change in the guidance. Specifically there has been:

- a change in recommendations on the use of pioglitazone and rosiglitazone where the combination of metformin and sulphonylurea is tolerated and not contraindicated, but has failed to achieve target HbA_{1c} levels
- a clarification of the Institute's position with regard to triple combination therapy

For people with type 2 diabetes, the use of a glitazone as second-line therapy added to either metformin or a sulphonylurea – as an alternative to treatment with a combination of metformin and a sulphonylurea – is not recommended except for those who are unable to take metformin and a sulphonylurea in combination because of intolerance or a contraindication to one of the drugs. In this instance, the glitazone should replace in the combination the drug that is poorly tolerated or contraindicated.

The effectiveness of glitazone combination therapy should be monitored against treatment targets for glycaemic control (usually in terms of haemoglobin A_{1c} [HbA_{1c}] level) and for other cardiovascular risk factors, including lipid profile. The target HbA_{1c} level should be set between 6.5% and 7.5%, depending on other risk factors.

The present UK licence does not allow the Institute to recommend the use of glitazones in triple combination therapy (with other oral antidiabetic agents), as monotherapy, or in combination with insulin. The use of a glitazone in triple combination (with other oral antidiabetic agents) is classified in the licence under 'special warnings and special precautions for use'. This precaution is based on the fact that at the time the licence was issued there was no clinical experience of triple combination therapy. When this guidance is reviewed the recommendations will take into account any extensions to the licence for the use of glitazones.

TECHNOLOGY APPRAISAL

Human growth hormone (somatropin) in adults with growth hormone deficiency

Issue date – August 2003 **Review date** – July 2006

Recombinant human growth hormone (somatropin) treatment is recommended for the treatment of adults with growth hormone (GH) deficiency only if they fulfil all three of the following criteria.

- They have severe GH deficiency, defined as a peak GH response of less than 9 mU/litre (3 ng/ml) during an insulin tolerance test or a cross-validated GH threshold in an equivalent test.
- They have a perceived impairment of quality of life (QoL), as demonstrated by a reported score of at least 11 in the disease-specific 'Quality of life assessment of growth hormone deficiency in adults' (QoL-AGHDA) questionnaire.
- They are already receiving treatment for any other pituitary hormone deficiencies as required.

The QoL status of people who are given GH treatment should be re-assessed 9 months after the initiation of therapy (an initial 3-month period of GH dose titration, followed by a 6-month therapeutic trial period). GH treatment should be discontinued for those people who demonstrate a QoL improvement of less than 7 points in QoL-AGHDA score.

Patients who develop GH deficiency in early adulthood, after linear growth is completed but before the age of 25 years, should be given GH treatment until adult peak bone mass has been achieved, provided they satisfy the biochemical criteria for severe GH deficiency (defined as a peak GH response of less than 9 mU/litre (3 ng/ml) during an insulin tolerance test or a cross-validated GH threshold in an equivalent test). After adult peak bone mass has been achieved, the decision to continue GH treatment should be based on all the criteria in the bullet points above.

Patients currently receiving GH treatment, for the management of adult onset GH deficiency, whether as routine therapy or as part of a clinical trial, could suffer loss of well being if their treatment were to be discontinued at a time they did not anticipate. Because of this, all NHS patients who are on therapy at the date of publication of this guidance should have the option to continue treatment until they and their consultant consider it is appropriate to stop.

Children with GH deficiency should be treated as outlined in the Institute's guidance on the use of GH in children (See *Human growth hormone [somatatropin] in children with growth failure* in this section). At completion of linear growth (that is, growth rate < 2 cm/year), GH treatment should be stopped for 2–3 months, and then GH status should be re-assessed. GH treatment at adult doses should be re-started only in those satisfying the biochemical criteria for severe GH deficiency (defined as a peak GH response of less than 9 mU/litre (3 ng/ml) during an insulin tolerance test or a cross-validated GH threshold in an equivalent test), and continued until adult peak bone mass has been achieved (normally around 25 years of age). After adult peak bone mass has been achieved, the decision to continue GH treatment should be based on all the criteria set out in the bullet points above.

Initiation of GH treatment, dose titration and assessment of response during trial periods should be undertaken by a consultant endocrinologist with a special interest in the management of GH disorders. Thereafter, if maintenance treatment is to be prescribed in primary care, it is recommended that this should be under an agreed shared care protocol.

Human growth hormone (somatropin) in children with growth failure

Issue date – May 2002 **Review date** – June 2005

Recombinant human growth hormone (somatropin) treatment is recommended for children with proven clinical diagnosis of growth hormone (GH) deficiency supported by appropriate auxological, biochemical and radiological investigations.

GH treatment is recommended for children with Turner syndrome (TS). The following issues should be taken into consideration in order to maximise the benefit from this treatment:

- diagnosis and treatment at earliest age possible
- appropriate timing and use of oestrogen therapy.

GH treatment is recommended for pre-pubertal children with (CRI) providing:

- nutritional status has been optimised
- metabolic abnormalities have been optimised
- steroid therapy has been reduced to minimum.

GH treatment is recommended for children with Prader-Willi syndrome.

GH treatment should, in all circumstances, be initiated and monitored by a paediatrician with special expertise in the management of children with GH disorder. Continuation of treatment can be maintained under an agreed shared-care protocol with a general practitioner.

GH treatment should be re-evaluated and normally discontinued if there is a poor response to treatment, defined as an increase in growth velocity of less than 50% from baseline, in the first year of therapy. Ongoing response should be evaluated against expected growth based on standard growth charts. Therapy should normally be stopped when final height is approached and growth velocity is less than 2 cm total growth in 1 year. Persistent and uncorrectable problems with adherence to treatment should also be taken into account as part of re-evaluation of treatment. In Prader-Willi syndrome evaluation of response to therapy should also consider body composition.

After attainment of final height, GH therapy will normally be discontinued, but it should not be discontinued by default. The decision to stop treatment should either be made by a paediatrician with special expertise in the management of children with GH disorders in consultation with patient and carers, or therapy should be continued until re-evaluation by an adult endocrinologist has been undertaken. The transition to adult care for people with GH disorders will require a close collaboration between the responsible clinicians.

In children with CRI, GH treatment should be stopped after renal transplantation. It should not normally be re-started until at least 1 year after renal transplantation to allow time to ascertain whether catch-up growth will occur.

The use of GH therapy in children with idiopathic short stature is currently not licensed, and therefore it was not considered as part of this appraisal.

INTERVENTIONAL PROCEDURE

Islet cell transplantation

Current evidence on the safety and efficacy of islet cell transplantation does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. Clinicians wishing to undertake islet cell transplantation should inform the clinical governance leads in their Trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for clinical audit and research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.

All cases should be registered with the International Islet Transplant Registry (ITR), which is based in Germany and run by Mathias D Brendel, Third Medical Department, University

Hospital Giessen, D-35385 Giessen, Germany (www.med.uni-giessen.de/itr/).

TECHNOLOGY APPRAISAL

Long-acting insulin analogues for the treatment of diabetes – insulin glargine

Issue date – December 2002 **Review date** – November 2005

Insulin glargine is recommended as a treatment option for people with type 1 diabetes.

Insulin glargine is not recommended for routine use for people with type 2 diabetes who require insulin therapy. Insulin glargine treatment should be considered only for those people with type 2 diabetes who require insulin therapy and who fall into one of the following categories.

- Those who require assistance from a carer or healthcare professional to administer their insulin injections.
- Those whose lifestyle is significantly restricted by recurrent symptomatic hypoglycaemic episodes.
- Those who would otherwise need twice-daily basal insulin injections in combination with oral antidiabetic drugs.

CLINICAL GUIDELINE (inherited)

Management of type 2 diabetes: management of blood glucose

Issue date – September 2002 **Review date** – September 2005

EVIDENCE LEVELS

The definitions of the type of evidence used in this guideline (Table 1) originate from the US Agency for Health Care Policy and Research.

Table 1 Levels of evidence

Level	Type of evidence
Ia	evidence from meta-analysis of randomised controlled trials
Ib	evidence from at least one randomised controlled trial
IIa	evidence from at least one controlled study without randomisation

Table 1 Levels of evidence (continued)

Level	Type of evidence
IIb	evidence from at least one other type of quasi-experimental study
III	evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case–control studies
IV	evidence from expert committee reports or opinions and/or clinical experience of respected authorities

Adapted from Agency for Health Care Policy and Research (1992) *Acute Pain Management: Operative or Medical Procedures and Trauma*. Rockville, MD, USA: Agency for Health Care Policy and Research/US Department of Health and Human Services, Public Health Service.

DERIVATION AND GRADING OF RECOMMENDATIONS

The grading scheme used in this guideline (Table 2) is from Eccles M et al. (1998).

Table 2 Grading of recommendations

Grade	Evidence
Ⓐ	directly based on category I evidence
Ⓑ	directly based on category II evidence, or extrapolated recommendation from category I evidence
Ⓒ	directly based on category III evidence, or extrapolated recommendation from category I or II evidence
Ⓓ	directly based on category IV evidence, or extrapolated recommendation from category I, II or III evidence

Eccles M et al. (1998) North of England Evidence Based Guideline Development Project: guideline for angiotensin converting enzyme inhibitors in primary care management of adults with symptomatic heart failure. *British Medical Journal* 316:1369.

MEASUREMENT

- People with type 2 diabetes should have ongoing structured evaluation of microvascular and cardiovascular risk and the development of complications. Ⓒ

- Haemoglobin A$_{1c}$ (HbA$_{1c}$) should be measured at 2–6 monthly intervals; the interval should depend on:
  - acceptable levels of control, Ⓓ **and**
  - stability of blood glucose control, Ⓓ **and/or**
  - change in levels of blood glucose, Ⓓ **and/or**
  - change in therapies. Ⓓ
- Six-monthly measurements should be made if the blood glucose level and blood glucose therapy are stable. Ⓓ
- If measurement of HbA$_{1c}$ is not possible because of abnormal erythrocyte turnover or haemoglobinopathy, blood glucose profiles and/or total glycated haemoglobin estimation should be used. Ⓓ
- HbA$_{1c}$ measurement should be DCCT aligned.* Ⓓ

* Glycated haemoglobin assays should be aligned with the HbA$_{1c}$ assay used in the Diabetes Control and Complications Trial (DCCT) and UKPDS, so that target blood glucose control can be related to the published long-term-vascular-risk findings. The majority of UK assays are now so aligned (Marshall and Barth 2000; Marshall et al. 2002).

Targets

- For each individual, a target HbA$_{1c}$ (DCCT aligned) should be set between 6.5% and 7.5%, based on the risk of macrovascular and microvascular complications. Ⓑ
- In general, the lower target HbA$_{1c}$ is preferred for people at significant risk of macrovascular complications, but higher targets are necessary for those at risk of iatrogenic hypoglycaemia. Ⓓ

Self-monitoring

- Self-monitoring should not be considered as a stand-alone intervention. Ⓓ
- Self-monitoring should be taught if the need/purpose is clear and agreed with the patient. Ⓓ
- Self-monitoring can be used in conjunction with appropriate therapy as part of integrated self-care. Ⓓ

Lifestyle interventions

- Weight loss and increased physical activity should be encouraged in those who are overweight or obese. Ⓑ
- Healthcare professionals should work with individuals to find approaches to lifestyle change that are likely to be adhered to and that give the best chance of success. Ⓓ
- The guideline developers noted that lifestyle changes can be difficult for some people to achieve or maintain. No single method appears to provide better results than any other.

Patient education

- Patient education should be offered on an ongoing basis. Different approaches should be tried until the best methods for the patient are identified from the attainment of desired outcomes. Ⓐ

The guideline developers reviewed the following approaches; they considered that while some studies show these approaches to have a beneficial impact on outcomes, other studies show them to have no impact on outcomes: computer-assisted learning; telephone-delivered education; patient activation and involvement; didactic teaching; individualised instruction; behaviour modification. The results from studies using a combination of approaches have been equivocal in terms of outcomes. See also 'Patient-education models for diabetes', in this section.

General therapy issues

- Concordance with therapy should be discussed with people with diabetes and monitored where the level of glucose control is problematic. Ⓓ
- Glucose-lowering therapies should be prescribed on a trial basis and the patient's response should be monitored using HbA_{1c} measurement (DCCT aligned). Ⓓ
- When glucose control deteriorates to unsatisfactory levels on current therapy, another therapy should normally be added, rather than substituted. Ⓑ

Metformin

- In people who are overweight (body mass index > 25.0 kg/m^2) and whose blood glucose is inadequately controlled using lifestyle interventions alone, metformin should normally be used as the first-line glucose-lowering therapy. Ⓐ
- Metformin should be considered as an option for first-line or combination therapy for people who are not overweight. Ⓐ
- Metformin is contraindicated in those with renal impairment (serum creatinine > 130 µmol/litre) and those at risk of sudden deterioration of renal function. Ⓒ

Insulin secretagogues

Insulin secretagogues include the sulphonylureas and the rapid-acting insulin secretagogues (nateglinide and repaglinide).

- Insulin secretagogues should be used in combination with metformin in overweight or obese people when glucose control becomes unsatisfactory. Ⓐ
- Insulin secretagogues should be considered as an option for first-line therapy when:
  - metformin is not tolerated or is contraindicated Ⓐ
  - people are not overweight. Ⓐ
- A generic sulphonylurea drug should normally be the insulin secretagogue of choice. Ⓑ
- Long-acting once-daily sulphonylureas may be useful where concordance with therapy is a suspected problem. Ⓑ
- Rapid-acting insulin secretagogues may have a role in attaining tight glucose control in patients with non-routine daily patterns. Ⓑ
- Clinicians and those using an insulin secretagogue should be aware of the risk of hypoglycaemia and be alert to it. Ⓐ

PPAR-γ agonists (including the thiazolidinediones)

- The currently available PPAR-γ agonists are the thiazolidinediones (commonly referred to as glitazones) pioglitazone and rosiglitazone.

- People should be offered a thiazolidinedione as oral combination therapy if:
  - they are unable to take metformin and insulin secretagogues as combination therapy, Ⓐ **or**
  - the HbA_{1c} level remains unsatisfactory despite an adequate trial of metformin with insulin secretagogues. Ⓐ
- The licensed thiazolidinediones are contraindicated in combination therapy with insulin. Ⓐ
- Further guidance on the use of rosiglitazone and pioglitazone for type 2 diabetes can be found in 'Pioglitazone for type 2 diabetes mellitus' and 'Rosiglitazone for type 2 diabetes mellitus' in this section.
- Note that if a licensed thiazolidinedione is prescribed to replace one glucose-lowering drug being used in combination with another, the withdrawal of one agent coupled with the slow onset of effectiveness of the licensed thiazolidinedione can result in a temporary but marked deterioration in blood glucose control.

Alpha-glucosidase inhibitors

- Acarbose may be considered as an alternative glucose-lowering therapy in people unable to use other oral drugs. Ⓐ

Insulins

- Insulin therapy should be offered to people with diabetes with inadequate blood glucose control on optimised oral glucose-lowering drugs. Ⓐ
- Local experience, patient preference and relative costs should inform the choice of insulin type and regimen as there is little research evidence in this area. Ⓓ
- Clinicians and people using insulin should be aware of the risk of hypoglycaemia and be alert to it. Ⓐ
- When transferring a person from a combination of metformin and another oral agent to insulin therapy, continue with metformin. Ⓑ
- When transferring a person from a combination of sulphonylurea plus another oral agent (metformin not

tolerated or contraindicated) to insulin therapy, continue the sulphonylurea. Ⓓ

Anti-obesity drugs

- Orlistat, when used in accordance with NICE guidance, may be considered as part of a weight-loss strategy for people with type 2 diabetes. Ⓐ

The relevant NICE guidance is as follows:

Orlistat should be available as one part of the management of obesity for adults who have lost 2.5 kg by diet and increased activity in the month prior to their first prescription and who also have a body mass index of 28 kg/m^2 or more and another serious illness that persists despite standard treatment (for example, type 2 diabetes, high blood pressure and/or high cholesterol).

[illegible]

Management of type 2 diabetes: management of blood pressure and blood lipids

Issue date – October 2002 **Review date** – October 2005

EVIDENCE LEVELS

The definitions of the type of evidence used in this guideline (Table 1) originate from the US Agency for Health Care Policy and Research.

Levels of evidence

Level	Type of evidence
Ia	evidence from meta-analysis of randomised controlled trials
Ib	evidence from at least one randomised controlled trial
IIa	evidence from at least one controlled study without randomisation
IIb	evidence from at least one other type of quasi-experimental study
III	evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case–control studies

Levels of evidence (continued)

Level	Type of evidence
IV	evidence from expert committee reports or opinions and/or clinical experience of respected authorities

DERIVATION AND GRADING OF RECOMMENDATIONS

The grading scheme used in this guideline (Table 2) is from Eccles M et al. (1998).

Table 2 Grading of recommendations

Grade	Evidence
Ⓐ	directly based on category I evidence
Ⓑ	directly based on category II evidence, or extrapolated recommendation from category I evidence
Ⓒ	directly based on category III evidence, or extrapolated recommendation from category I or II evidence
Ⓓ	directly based on category IV evidence, or extrapolated recommendation from category I, II or III evidence

Eccles M et al. (1998) North of England Evidence Based Guideline Development Project: guideline for angiotensin converting enzyme inhibitors in primary care management of adults with symptomatic heart failure. *British Medical Journal* 316:1369.

Assessment and management of overall cardiovascular disease risk for all people with type 2 diabetes

- At diagnosis, take a full clinical history, including any history of cardiovascular disease. Ⓓ
- Arrange recall and at least annual review for all people with type 2 diabetes. Ⓓ
- Estimate coronary heart disease risk at least annually for all people without manifest cardiovascular disease. Ⓒ
- Use risk assessment charts (such as the Joint Societies Charts in the *British National Formulary*) to estimate 10-year coronary event risk. Ⓓ (See Box 1)
- Classify people with manifest cardiovascular disease as being at higher 10-year coronary event risk. Ⓒ (See Box 1)

- Maintain tight blood glucose control (haemoglobin A_{1c} below 6.5% to 7.5% according to an individual's target and level of coronary event risk) and manage according to the guideline in this series (see 'Management of type 2 diabetes: management of blood glucose' in this section). Ⓐ
- Screen for renal disease and manage according to the renal guideline in this series (see 'Management of type 2 diabetes: renal disease – prevention and early management' in this section). Ⓑ
- Measure blood pressure and manage according to the guideline in this series (see 'Management of type 2 diabetes: management of blood pressure and blood lipids' in this section). Ⓑ
- Measure lipid profile and manage according to the guideline in this series (see 'Management of type 2 diabetes: management of blood pressure and blood lipids' in this section). Ⓑ
- Review and discuss other modifiable risk factors, particularly smoking. Ⓑ
- Offer smoking cessation advice where appropriate. Ⓒ
- Offer lifestyle management advice. Ⓒ *(For further details of the evidence, see the blood glucose management guideline in this section.)*
- For individuals who are overweight or obese, encourage weight loss and increased physical activity. Ⓐ *(For further details of the evidence, see the blood glucose management guideline in this section.)*

Box 1. 10-year coronary event risk

For purposes of this guideline higher and lower 10-year coronary event risk are defined as follows.

A person at **higher risk** is one:

- who has manifest cardiovascular disease (a history or symptoms of coronary heart disease, stroke or peripheral vascular disease) or
- whose 10-year coronary event risk is assessed as above 15%, taking into account the known limitations of the risk

assessment charts (see *British National Formulary* 2002; 43).

A person at **lower risk** is one:

- who does not have manifest cardiovascular disease **and**
- whose 10-year coronary event risk is 15% or below, taking into account the known limitations of the risk assessment charts (see *British National Formulary* 2002; 44).

Management of blood pressure

ASSESSING BLOOD PRESSURE

- Measure blood pressure according to standard practice. Ⓓ*

*The accepted methods for the measurement of blood pressure are set out in the guidelines of the British Hypertension Society – see Ramsay L, et al. (1999) 'Guidelines for management of hypertension: report of the third working party of the British Hypertension Society'. *Journal of Human Hypertension*; **13**: 569–592.

MANAGEMENT FOR PEOPLE WITH BLOOD PRESSURE BELOW 140/80 MMHG

- Monitor blood pressure on an annual basis. Ⓓ
- If blood pressure is raised, at or above 140/80 mmHg, take two further readings over a period of 2 months, or sooner if clinical circumstances dictate. Ⓓ
- If blood pressure is subsequently persistently raised, at or above 140/80 mmHg, manage according to the recommendations below. Ⓑ

MANAGEMENT FOR PEOPLE WITH BLOOD PRESSURE OF 140/80 MMHG AND ABOVE

For all people with blood pressure of 140/80 mmHg and above:

- offer lifestyle management advice to minimise subsequent blood pressure increase, Ⓓ
- use an average of three blood pressure recordings to determine baseline blood pressure measurement, Ⓓ
- monitor blood pressure every 6 months, or more frequently according to an individual's requirements. Ⓓ

Table 3 shows the recommendations for pharmacological management for people with raised blood pressure (140/80 mmHg and above) with or without a higher 10-year coronary event risk or albuminuria/proteinuria.

NOTE

Prescribers are advised to consult the *British National Formulary* for precautions and contraindications before initiating the drug treatment referred to in this guidance. Full information on individual drugs is available in the Summary of Product Characteristics.

Table 3 Recommendations for pharmacological management of raised blood pressure in people with type 2 diabetes

	Blood pressure	**10-year coronary event risk (see Box 1, page 51)**	**Concomitant micro-albuminuria or proteinuri**
1	≥ 140/80 mmHg and < 160/100 mmHg	Lower (no history of CVD **and** 10-year coronary event risk ≤ 15%)	No
2	≥ 140/80 mmHg and < 160/100 mmHg	Higher (history of CVD or 10-year coronary event risk > 15%)	No
3	≥ 160/100 mmHg	Higher or lower	No
4*	≥ 140/80 mmHg	Higher or lower	Yes

* The recommendations in (4) are from the guideline on renal care in this section
See below for recommendations on anti-platelet therapy

Box 2 Recommendations on choice of pharmacological therapy to reduce blood pressure

- Use ACE inhibitors (see Box 3), angiotensin II receptor antagonists, beta blockers or thiazide diuretics as first-line treatments in people who do not have microalbuminuria. Ⓐ
- Long-acting dihydropyridine and non-dihydropyridine calcium-channel blockers have an important role in treating blood pressure, but on current evidence should be prescribed as second-line treatment or as part of combination therapy. Ⓑ

commendations
nitor blood pressure every 6 months or more frequently if necessary. Ⓓ 0-year coronary event risk is subsequently found to have increased to the her risk level, treat according to (2) below. Ⓒ lood pressure rises to a level persistently equal to or greater than)/100 mmHg, treat according to (3) below. Ⓒ
er pharmacological treatment to reduce blood pressure. Ⓑ (See Box 2) n for a target blood pressure below 140/80 mmHg. Ⓑ
er pharmacological treatment to reduce blood pressure. Ⓑ (See Box 2) n for a target blood pressure below 140/80 mmHg. Ⓑ
er pharmacological treatment to achieve a target blood pressure equal to ess than 135/75 mmHg. Ⓑ e ACE inhibitors as the class of first choice to treat people with croalbuminuria or proteinuria. Ⓐ (See Box 2) here ACE inhibitors are unsuitable or are contraindicated in people with croalbuminuria or proteinuria, then angiotensin II receptor antagonists y be considered as alternative first-line therapy. Ⓑ (See Box 2) ug classes that may be used in combination therapy with ACE inhibitors angiotensin II receptor antagonists include beta blockers, long-acting cium channel blockers or thiazide diuretics. Ⓑ

- Do not prescribe short-acting calcium-channel blockers. Ⓓ
- Anticipate that combination therapy with any or all of these drug classes will be required to meet treatment targets in the majority of people. Ⓒ
- Assess the response to treatment frequently (every 3 to 6 months when stabilised, more frequently when titrating treatment). Ⓓ

Box 3 Starting ACE inhibitor therapy for patients*:

- caution in patients with peripheral vascular disease/renovascular disease
- caution in patients with raised serum creatinine.

In all patients, measure serum creatinine and electrolytes 1 week after:

- initiating ACE inhibitor therapy
- each increase in dose.

* Some ACE inhibitors are not licensed for use at the blood pressure levels at which they are recommended in this guideline. See cautions in the *British National Formulary*.

Management of blood lipids

ASSESSING LIPID PROFILE AT DIAGNOSIS

- When type 2 diabetes is diagnosed, measure total cholesterol (TC), low-density lipoprotein (HDL-C), high-density lipoprotein (LDL-C) and triglycerides (TG). Ⓒ
- Use fasting measurement of lipids if feasible. Ⓒ

FOR PEOPLE WITH NORMAL LIPID PROFILE

For people with total cholesterol less than 5.0 mmol/litre (or LDL-C less than 3.0 mmol/litre) **and** triglycerides less than 2.3 mmol/litre:

- annually measure total cholesterol and LDL-C and – if fasting measurements are feasible – HDL-C and triglycerides, Ⓓ
- no pharmacological treatment is recommended. Ⓑ

INITIAL ASSESSMENT AND GENERAL MANAGEMENT FOR PEOPLE WITH AN ADVERSE LIPID PROFILE

Initial assessment should be as follows for people with total cholesterol 5.0 mmol/litre or higher (or LDL-C 3.0 mmol/litre or higher) **or** triglycerides 2.3 mmol/litre **or** higher.

- On first assessment, to identify people with an adverse lipid profile secondary to conditions other than diabetes mellitus:
  - ask about alcohol consumption and manage accordingly, Ⓒ
  - check thyroid function tests to exclude hypothyroidism, Ⓒ
  - check liver function tests to exclude liver disease, Ⓒ
  - check serum creatinine and urine protein to exclude renal disease. Ⓒ (This is a standard part of assessment, together with testing for urine protein – see the renal disease guideline in this section.)

General management for people with an adverse lipid profile should be as follows.

- Optimise glycaemic control (preferably to haemoglobin A_{1c} below 6.5%). Ⓒ
- Offer intensive advice on diet and physical activity to all patients and advice on weight loss to those who are overweight or obese. Ⓑ
- Before starting any pharmacological treatment for abnormal lipid profile, measure fasting levels of total cholesterol, HDL-C, LDL-C and triglycerides as a baseline. Ⓒ
- If the lipid profile remains abnormal, consider pharmacological therapy. Ⓓ
- Monitoring of lipids after treatment starts should preferably be done with fasting blood samples to measure total cholesterol, HDL-C, LDL-C and triglycerides, but when it is not feasible to obtain fasting samples it is acceptable to monitor using total cholesterol and HDL-C levels in non-fasting samples. Ⓓ

Recommendations for pharmacological therapy for people with an adverse lipid profile

Table 4 shows the recommendations for the pharmacological

Table 4 Recommendations for pharmacological management of adverse lipid profiles in people with type 2 diabetes

	Blood lipid profile at start of therapy	10-year coronary event risk (see Box 1, page 51)
1	TC ≥ 5.0 mmol/litre (or LDL-C ≥ 3.0 mmol/litre) **or** TG ≥ 2.3 mmol/litre and < 10 mmol/litre	Lower (no history of CVD **and** 10-year coronary event risk ≤ 15%)
2	TC ≥ 5.0 mmol/litre (or LDL-C ≥ 3.0 mmol/litre) **or** TG ≥ 2.3 mmol/litre and <10 mmol/litre	Higher: 10-year coronary event risk > 15% **but** no history of CV
3	TC ≥ 5.0 mmol/litre (or LDL-C ≥ 3.0 mmol/litre) **or** TG ≥ 2.3 mmol/litre and < 10 mmol/litre	Higher: manifest CVD
4	TC < 5.0 mmol/litre (or LDL-C < 3.0 mmol/litre) **and** TG ≥ 2.3 mmol/litre and <10 mmol/litre	Higher: manifest CVD
5	Fasting TG ≥ 10 mmol/litre	Higher or lower

CHD, coronary heart disease; CVD, cardiovascular disease; LDL-C, low-density lipoprotein; TC, total cholesterol; TG, triglycerides

Recommendations

Discuss CHD risk with the patient, and consider whether treatment is appropriate at the time when type 2 diabetes is diagnosed. D

Consider offering drug therapy at higher levels of cholesterol or triglyceride D

Following a decision to start treatment:

- offer a statin, B
- assess the effect of statin therapy within 3 months and titrate the dose if required, D
- monitor the effect of therapy annually. D

If a decision is made **not** to start pharmacological therapy, monitor lipid profile and cardiovascular risk annually, to consider the need for therapy. D

Primary prevention

Offer a statin. B

Assess the effect of statin therapy within 3 months and titrate the dose if required. D

Monitor the effect of therapy annually. D

Secondary prevention

Offer a statin. B

Assess the effect of statin therapy within 3 months and titrate the dose if required. D

Consider adding a fibrate after 6 months if triglyceride remains ≥ 2.3 mmol/litre. D

Ensure there is no evidence of drug interaction between the proposed choices of fibrate and statin preparation. C *

Monitor the effect of therapy annually. D

Secondary prevention

Offer a statin B or a fibrate C

Assess the effect of statin therapy within 3 months and titrate the dose if required. D

Monitor the effect of therapy annually. D

Offer fibrate therapy and consider referral to a diabetes or lipid clinic. D management for people with an adverse lipid profile with or without a higher 10-year coronary event risk.

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* Use of a statin and fibrate together increases the likelihood of adverse effects (see *British National Formulary* 2002; 44)

There is evidence from clinical studies of benefits of pharmacological intervention for patients aged up to 69 years for primary prevention and up to 75 years for secondary prevention. However, these guidelines do not recommend age-related restrictions on the use of pharmacological therapy.

Target thresholds for pharmacological treatment: The target threshold for cholesterol should be, at a minimum, to reduce total cholesterol to below 5.0 mmol/litre or by 20–25%, whichever is lower **or** to reduce LDL-C to below 3.0 mmol/litre or by 30%, whichever is lower, although further benefit will accrue at lower treatment target levels.

Anti-platelet therapy for people with higher 10-year coronary risk

The recommendations for anti-platelet therapy for people with higher 10-year coronary risk, regardless of blood pressure blood lipid levels, are as follows.

- Secondary prevention
  - For people with manifest cardiovascular disease, offer 75 mg aspirin daily. Ⓑ
- Primary prevention
  - For people with a 10-year coronary risk of greater than 15%, offer 75 mg aspirin daily. Ⓐ
  - Before starting aspirin therapy for this group of people, reduce systolic blood pressure to 145 mmHg or below and maintain while taking aspirin for primary prevention. Ⓑ
- Prescribe aspirin according to the recognised cautions and contraindications given in the British National Formulary. Ⓓ

CLINICAL GUIDELINE (INHERITED)

Management of type 2 diabetes: renal disease – prevention and early management

Issue date – February 2002 **Review date** – March 2005

EVIDENCE LEVELS

The definitions of the type of evidence used in this guideline originate from the US Agency for Health Care Policy and Research.

Levels of evidence

Level	Type of evidence
Ia	evidence from meta-analysis of randomised controlled trials
Ib	evidence from at least one randomised controlled trial
IIa	evidence from at least one controlled study without randomisation
IIb	evidence from at least one other type of quasi-experimental study
III	evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case–control studies
IV	evidence from expert committee reports or opinions and/or clinical experience of respected authorities

GRADING OF RECOMMENDATIONS

The grading scheme used in this guideline is from Eccles M et al. (1998).

Grading of recommendations

Grade	Evidence
Ⓐ	directly based on category I evidence
Ⓑ	directly based on category II evidence, or extrapolated recommendation from category I evidence
Ⓒ	directly based on category III evidence, or extrapolated recommendation from category I or II evidence
Ⓓ	directly based on category IV evidence, or extrapolated recommendation from category I, II or III evidence

Eccles M et al. (1998) North of England Evidence Based Guideline Development Project: guideline for angiotensin converting enzyme inhibitors in primary care management of adults with symptomatic heart failure. *British Medical Journal* 316:1369.

Definitions used in this guideline

Diabetic renal disease

The presence of raised urine albumin levels and/or raised serum creatinine in type 2 diabetes indicates an increased risk of premature cardiovascular events and, to a lesser extent, end-stage renal disease. If the person also has signs of retinopathy, it is likely that the raised urine albumin and/or raised serum creatinine is resulting from diabetes-related renal disease. If retinopathy is not present, the probability of another renal disease increases.

Lower-risk urine albumin excretion

People who have levels of **microalbuminuria** and/or **proteinuria** lower than those indicated below.

Higher-risk urine albumin excretion

Microalbuminuria – albumin:creatinine ratio greater than or equal to 2.5 mg/mmol (men) or 3.5 mg/mmol (women), or albumin concentration greater than or equal to 20 mg/l

and/or

Proteinuria – albumin:creatinine ratio greater than or equal to 30 mg/mmol or albumin concentration greater than or equal to 200 mg/l.

GUIDANCE

Diabetes

Type 2 diabetes is affecting increasing numbers of people in the UK and the burden of serious complications and their sequelae can be considerable both for the individual concerned and the health service in general. Many aspects of these complications can be limited, even prevented in some instances, with good early management of the condition. The aim of these guidelines is to provide guidance about managing type 2 diabetes for people with diabetes and the whole range of clinical staff who work in primary and secondary care, in order to maximise the potential for reducing complications and improving the quality of life of people with the disease.

This guideline is one of a series of five guidelines on type 2 diabetes.

Diabetic renal disease

Microalbuminuria is the earliest indicator of renal disease (nephropathy) attributable to diabetes. Microalbuminuria relates to a range of albumin values in the urine that, while low, are above normal levels. A review of longitudinal studies has shown microalbuminuria to be predictive of total mortality, cardiovascular mortality and cardiovascular morbidity.

Proteinuria, or macroalbuminuria, relates to a more extreme increase in the level of albumin in the urine. It represents a progression of urine albumin excretion from microalbuminuria. There is no definitive level of albumin to describe a clear cut-off point for proteinuria in the literature. There is also overlap between the albumin ranges used to define microalbuminuria and the cut-off points for proteinuria across some studies.

People with type 2 diabetes can progress from proteinuria to end-stage renal failure, though this outcome is rare in comparison with cardiovascular mortality and morbidity.

RENAL CARE FOR ALL PEOPLE WITH TYPE 2 DIABETES

- Arrange recall and annual review for people with type 2 diabetes. Ⓒ
- Review complications and risk factors at diagnosis and at least annually thereafter. Ⓒ
- Measure urinary albumin:creatinine ratio or albumin concentration annually. Ⓒ
  - Use a first morning urine sample where practicable. Ⓒ
  - Use a laboratory or near-patient test specifically for microalbuminuria. Ⓒ
- If microalbuminuria or proteinuria is present, repeat twice more (within 1 month where possible). Ⓒ
- Measure serum creatinine annually. Ⓒ
- Classify albumin excretion annually as:
  - lower risk (absence of microalbuminuria or proteinuria), Ⓒ **or**
  - higher risk (see ‘definitions’ above). Ⓒ

CARE FOR PEOPLE WITH LOWER-RISK ALBUMIN EXCRETION

- Maintain good blood glucose control (preferably HbA_{1c} below 6.5–7.5%, according to the individual's target). Ⓐ
- Maintain good blood pressure control (target blood pressure at or below 140/80 mmHg). Ⓐ

CARE FOR PEOPLE WITH HIGHER-RISK URINE ALBUMIN EXCRETION

- If retinopathy is not present, look for a non-diabetes-related cause of renal disease (full history and examination, urinalysis, renal ultrasound, other investigations as appropriate). Ⓒ
- Ensure good blood glucose control (HbA_{1c} below 6.5–7.5%, according to the individual's target). Ⓐ
- Measure, assess and manage cardiovascular risk factors aggressively. Ⓐ
- Maintain blood pressure below 135/75 mmHg. Ⓐ
- Begin therapy with an appropriate ACE inhibitor for cardiovascular/renal protection (see box below). Ⓐ
- ACE inhibitors are the drug class of first choice. To achieve target blood pressure, use combination therapy if ACE inhibitors alone are not fully effective. Combination therapy is likely to be necessary for most patients. Ⓐ
- Measure urine albumin and serum creatinine levels at each visit. Ⓒ
- Refer for specialist/nephrological opinion if serum creatinine greater than 150 µmol/l. Ⓓ

Starting ACE inhibitor therapy[a] in people with type 2 diabetes

ACE inhibitor therapy should be used with caution in those with:

- peripheral vascular disease/renovascular disease
- raised serum creatinine.

For all people with type 2 diabetes, measure serum creatinine and electrolytes 1 week after:

- initiating ACE inhibitor therapy
- each increase in dose.

[a]: Some ACE inhibitors are not licensed for use at the blood pressure levels recommended in this guideline.

Management of type 2 diabetes: retinopathy – early management and screening

Issue date – February 2002 **Review date** – March 2005

EVIDENCE LEVELS

The definitions of the type of evidence used in this guideline originate from the US Agency for Health Care Policy and Research.

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Ⓒ	directly based on category III evidence, or extrapolated recommendation from category I or II evidence
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Eccles M et al. (1998) North of England Evidence Based Guideline Development Project: guideline for angiotensin converting enzyme inhibitors in primary care management of adults with symptomatic heart failure. *British Medical Journal* 316:1369.

GUIDANCE

Diabetes

Type 2 diabetes is affecting increasing numbers of people in the UK and the burden of serious complications and their sequelae can be considerable both for the individual concerned and the health service in general. Many aspects of these complications can be limited, even prevented in some instances, with good early management of the condition. The aim of these guidelines is to provide guidance about managing type 2 diabetes for people with diabetes and the whole range of clinical staff who work in primary and secondary care, in order to maximise the potential for reducing complications and improving the quality of life of people with the disease.

This guideline is one of a series of five guidelines on type 2 diabetes.

Diabetic retinopathy

Diabetic retinopathy is the leading cause of blindness in people under the age of 60 in industrialised countries. It is also a major cause of blindness in older people.

Many people will be asymptomatic until the disease is very advanced. After 20 years from onset of diabetes, more than 60% of people with type 2 diabetes will have diabetic retinopathy. In people with type 2 diabetes, maculopathy is the major cause of visual loss.

The risk of visual impairment and blindness is substantially reduced by a care programme that combines methods for early detection with effective treatment of diabetic retinopathy. The key issue in screening for diabetic retinopathy is to identify those people with sight-threatening retinopathy who may require preventive treatment.

Screening and treatment for diabetic retinopathy will not eliminate all cases of sight loss, but can play an important part in minimising the numbers of patients with sight loss due to retinopathy.

EYE CARE FOR ALL PEOPLE WITH DIABETES

- Maintain good blood pressure control (at or below 140/80 mmHg). Ⓐ
- Maintain good blood glucose levels (preferably below HbA_{1c} 6.5–7.5%, according to the individual's target). Ⓐ
- Check visual acuity, corrected with glasses or pinhole. Ⓓ
- Refer for specialist opinion if cataracts are interfering with vision or the retina is obscured. Ⓓ
- Classify eye care as: **routine care** required; **early review** required; or **referral** required (see below). Ⓓ

Screening for diabetic retinopathy

- Examine the eyes of people with type 2 diabetes at the time of diagnosis and at least annually thereafter (including those registered blind and partially sighted). Ⓓ
- Perform an appropriate and acceptable retinopathy screening test. Ⓓ
- Use tests that have been demonstrated to achieve: sensitivity of 80% or higher; specificity of 95% or higher; and technical failure rate of 5% or lower. Ⓒ
  - Retinal photography, which is currently the most practical method, when conducted and evaluated by trained personnel, Ⓒ or slit-lamp indirect ophthalmoscopy, which is effective in trained hands. Ⓒ

- Use tropicamide (to achieve mydriasis) unless contraindicated. Ⓒ
- Opportunistic screening is not an adequate substitute for participation in a formal screening programme. It is an option only if formal screening is not possible. Ⓓ

Routine care

- Review annually if:
  - no retinopathy present Ⓓ
  - minimal or mild background retinopathy[1]/low-risk background retinopathy. Ⓓ

Early review

- Review every 3 to 6 months if:
  - lesions have occurred or worsened since last examination Ⓓ
  - there are scattered exudates more than 1 disc diameter from the fovea Ⓓ
  - the person is at high risk of progression (rapid improvement in blood glucose control, presence of hypertension or renal disease). Ⓓ

Referral

Refer to an ophthalmology specialist if:

****	there is sudden loss of vision Ⓓ
****	there is evidence of retinal detachment Ⓓ
***	there is new vessel formation Ⓓ
***	there is evidence of preretinal and/or vitreous haemorrhage Ⓓ
***	rubeosis iridis is present Ⓓ
**	there is an unexplained drop in visual acuity Ⓓ
**	there are hard exudates within 1 disc diameter of the fovea Ⓓ
**	there is macular oedema Ⓓ
**	there are unexplained retinal findings Ⓓ
**	pre-proliferative or more advanced (severe) retinopathy is present. Ⓓ

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[1]: Mild non-proliferative diabetic retinopathy is described in the Royal College of *Ophthalmology's Guidelines for Diabetic Retinopathy* (1997).

The Guideline Development Group considers the following maximum waiting times to be appropriate, though health authorities, trusts and primary care organisations should work to the locally defined waiting time for appointments to see a specialist soon (**) or urgently (***).

****	The individual should be seen by a specialist **immediately**, within **1 day**.
***	The individual should be seen by a specialist **urgently**, with a maximum waiting time of **1 week**.
**	The individual should be seen by an ophthalmology specialist **soon**, with a maximum waiting time of **4 weeks**.

Patient-education models for diabetes

Issue date – April 2003 **Review date** – February 2006

It is recommended that structured patient education is made available to all people with diabetes at the time of initial diagnosis and then as required on an ongoing basis, based on a formal, regular assessment of need.

There is insufficient evidence currently available to recommend a specific type of education or provide guidance on the setting for, or frequency of, sessions. However, to achieve maximum effectiveness some principles of good practice are clear:

- educational interventions should reflect established principles of adult learning
- education should be provided by an appropriately trained multidisciplinary team to groups of people with diabetes, unless group work is considered unsuitable for an individual
- sessions should be accessible to the broadest range of people, taking into account culture, ethnicity, disability and geographical issues, and could be held either in the community or at a local diabetes centre
- educational programmes should use a variety of techniques to promote active learning (engaging individuals in the process of learning and relating the content of programmes

to personal experience), adapted wherever possible to meet the different needs, personal choices and learning styles of people with diabetes, and should be integrated into routine diabetes care over the longer term.

Multidisciplinary teams providing education should include, as a minimum, a diabetes specialist nurse (or a practice nurse with experience in diabetes) who has knowledge of the principles of patient education and a dietitian. Although not formally assessed in this appraisal, input from other disciplines, such as podiatry, has potential value. The composition of the team and the way that members interact may vary between programmes, but team functioning should be tailored to the needs of different groups of people with diabetes.

It is considered that the Dose Adjustment for Normal Eating (DAFNE) programme may be a suitable option for individuals with type 1 diabetes, being one means of enabling people to self-manage this condition.

Eye

Technology Appraisal

Photodynamic therapy for age-related macular degeneration 120 NEW

TECHNOLOGY APPRAISAL

Photodynamic therapy for age-related macular degeneration

Issue date – September 2003 **Review date** – September 2006

Photodynamic therapy (PDT) is recommended for the treatment of wet age-related macular degeneration for individuals who have a confirmed diagnosis of classic with no occult subfoveal choroidal neovascularisation (CNV) (that is, whose lesions are composed of classic CNV with no evidence of an occult component) and best-corrected visual acuity 6/60 or better. PDT should be carried out only by retinal specialists with expertise in the use of this technology.

PDT is not recommended for the treatment of people with predominantly classic subfoveal CNV (that is, 50% or more of the entire area of the lesion is classic CNV but some occult CNV is present) associated with wet age-related macular degeneration, except as part of ongoing or new clinical studies that are designed to generate robust and relevant outcome data, including data on optimum treatment regimens, long-term outcomes, quality of life and costs.

The use of PDT in occult CNV associated with wet age-related macular degeneration was not considered because the photosensitising agent (verteporfin) was not licensed for this indication when this appraisal began. No recommendation is made with regard to the use of this technology in people with this form of the condition.

Patients currently receiving treatment with PDT could experience loss of well-being if their treatment is discontinued at a time they did not anticipate. Because of this, all NHS patients who have begun a course of treatment with PDT at the date of publication of this guidance should have the option of continuing to receive treatment until their clinical condition indicates that it is appropriate to stop.

Gastrointestinal

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Infliximab for Crohn's disease 122

Laparoscopic surgery for inguinal hernia 123

Proton pump inhibitors for dyspepsia 123

TECHNOLOGY APPRAISAL

Infliximab for Crohn's disease

Issue date – April 2002 **Review date** – May 2005

Infliximab is recommended for the treatment of patients with severe Crohn's disease who fulfil all three of the following criteria:

- Patients who have severe active Crohn's disease. These patients will already be in very poor general health with weight loss and sometimes fever, severe abdominal pain and usually frequent (3–4 or more) diarrhoeal stools daily. They may or may not be developing new fistulae or have extra-intestinal manifestations of the disease. This clinical definition normally corresponds to a Crohn's Disease Activity Index (CDAI) score of 300 or more and a Harvey-Bradshaw Index of 8/9 or above;
- Patients whose condition has proved to be refractory to treatment with immunomodulating drugs (e.g. azathioprine or 6-mercaptopurine, methotrexate) and corticosteroids, or who have been intolerant of, or experienced toxicity from, these treatments.
- Patients for whom surgery is inappropriate (e.g. because of diffuse disease and/or a risk of short bowel syndrome).

Treatment can be repeated for those patients who match the above criteria and have responded to the initial treatment course, but then relapsed. A decision about whether or not to re-administer infliximab after the first course or subsequently should be made only after discussion with the patient who has been fully informed of the potential risks and benefits of repeated therapy (episodic treatment).

Infliximab should be prescribed by a gastroenterologist experienced in the management of Crohn's disease.

Infliximab is not recommended for patients with fistulising Crohn's disease who do not have the other criteria for severe active Crohn's disease as detailed above.

TECHNOLOGY APPRAISAL

Laparoscopic surgery for inguinal hernia

Issue date – January 2001 **Review date** – August 2003

For repair of primary inguinal hernia, open (mesh) should be the preferred surgical procedure.

For the repair of recurrent and bilateral inguinal hernia, laparoscopic surgery should be considered.

When laparoscopic surgery is undertaken for inguinal hernia, the totally extraperitoneal (TEP) procedure should be preferred.

Laparoscopic surgery for inguinal hernia should only be undertaken in those units with appropriately trained operating teams which regularly undertake these procedures.

TECHNOLOGY APPRAISAL

Proton pump inhibitors for dyspepsia

Issue date – July 2000 **Review date** – June 2003

In patients with documented duodenal or gastric ulcers, a treatment strategy of testing for *Helicobacter pylori* and, where positive, eradicating the infection is recommended. Long-term acid-suppressing therapy should not be used. Those patients who are *H.pylori* negative or remain symptomatic after eradication therapy should be treated as described below.*

For patients with a documented non steroidal anti-inflammatory drug (NSAID)-induced ulcer, who must unavoidably continue with NSAID therapy (e.g. those with severe rheumatoid arthritis), an acid suppressor, usually a proton pump inhibitor (PPI), should be prescribed. After the ulcer has healed, the patient, where possible, should be stepped down to a maintenance dose of the acid suppressor.

Patients who have severe gastro-oesophageal reflux disorder (GORD) symptoms or who have a proven pathology (e.g. oesophageal ulceration, Barrett's oesophagus) should be treated with a healing dose of a PPI until symptoms have been controlled. After that has been achieved, the dose should be stepped down to the lowest dose that maintains control of symptoms. A regular maintenance low dose of most PPIs will prevent recurrent GORD symptoms in 70–80% of patients and should be used in preference to the higher healing dose. Where necessary, should symptoms re-appear, the higher dose should be recommenced. In complicated oesophagitis (stricture, ulcer, haemorrhage) the full dose should be maintained. Patients with mild GORD symptoms and/or those who do not have a proven pathology can frequently be managed by alternative therapies (at least in the first instance) including antacids, alginates, or H_2RAs (H_2 receptor antagonists).

Patients diagnosed with non-ulcer dyspepsia (NUD) may have symptoms caused by different aetiologies and should not be routinely treated with PPIs. Should the symptoms appear to be acid-related, an antacid or the lowest dose of an acid suppressor to control symptoms should be prescribed. If they do not appear to be acid-related, an alternative therapeutic strategy should be employed.

Patients presenting in general practice with mild symptoms of dyspepsia may be treated on either a 'step-up' or a 'step-down' basis. Neither group should normally be treated with PPIs on a long-term basis without a confirmed clinical diagnosis being made.

*In circumstances where it is appropriate to use a PPI and where healing is required, the optimal dose to achieve this should be prescribed initially. Once healing has been achieved, or for conditions where it is not required, the lowest dose of the PPI that provides effective symptom relief should be used.

The least expensive appropriate PPI should be used.

The use of PPIs outlined in the paragraphs above refers for each indication only to those PPIs which have been licensed for that use.

On present evidence, PPIs do not have any serious contraindications for the vast majority of users, and have been in common use for some eight or nine years. While their use in sufficient dosage to cure, or to control symptoms, is well warranted in terms of their clear benefits, any additional use cannot be recommended.

[illegible]

Sacral nerve stimulation for faecal incontinence

Issue date – August 2003

Current evidence of the safety and efficacy of sacral nerve stimulation for faecal incontinence does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake sacral nerve stimulation for faecal incontinence should inform the clinical governance leads in their trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty.

It is recommended that the procedure is performed only in centres where full anorectal investigation is available.

NICE has commissioned a systematic review of sacral nerve stimulation for faecal incontinence, together with sacral nerve stimulation for urge incontinence.

Gynaecology, pregnancy and childbirth

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CLINICAL GUIDELINE

Antenatal care: routine care for the healthy pregnant woman

Issue date – October 2003 **Review date** – October 2007

The following guidance is evidence based. The grading scheme and hierarchy of evidence used in this guideline (see Table) is adapted from Eccles and Mason (2001).

Recommendation Grade	Evidence
Ⓐ	directly based on category I evidence
Ⓑ	directly based on • category II evidence, or • extrapolated recommendation from category I evidence
Ⓒ	directly based on • category III evidence, or • extrapolated recommendation from category I or II evidence
Ⓓ	directly based on • category IV evidence, or • extrapolated recommendation from categoryI, II or III evidence
Good practice point (GPP)	The view of the Guideline Development Group
NICE 2002	Recommendation taken from the NICE technology appraisal

Evidence category	Source
Ia	Systematic review and meta-analysis of randomised controlled trials
Ib	At least one randomised controlled trial
IIa	At least one well-designed controlled study without randomisation

Evidence category	Source
IIb	At least one other type of well-designed quasi-experimental studyIII Well-designed non-experimental descriptive studies, such as comparative studies, correlation studies or case studies
IV	Expert committee reports or opinions and/or clinical experience of respected authorities

Adapted from Eccles M, Mason J (2001) How to develop cost-conscious guidelines. *Health Technology Assessment* 5:16.

The guidance covers baseline care for all pregnant women. Some women will require care additional to that described. (see Table 1)

Table 1 Women requiring additional care

Pregnant women with the following conditions usually require care additional to that detailed in this guideline:

- cardiac disease, including hypertension
- renal disease
- endocrine disorder or diabetes requiring insulin
- psychiatric disorder (on medication)
- haematological disorder, including thromboembolic disease, autoimmune diseases such as antiphospholipid syndrome
- epilepsy requiring anticonvulsant drugs
- malignant disease
- severe asthma
- drug use such as heroin, cocaine (including crack cocaine) and ecstasy
- HIV or HBV infected
- autoimmune disorders
- obesity (BMI 35 or more at first contact) or underweight (BMI less than 18 at first contact)
- women who may be at higher risk of developing complications e.g. women 40 years and older and women who smoke
- women who are particularly vulnerable (e.g. teenagers) or who lack social support.

Women who have experienced any of the following in previous pregnancies:

- recurrent miscarriage (three or more consecutive pregnancy losses) or a mid-trimester loss
- severe pre-eclampsia, HELLP syndrome or eclampsia
- rhesus isoimmunisation or other significant blood group antibodies
- uterine surgery including caesarean section, myomectomy or cone biopsy
- antenatal or postpartum haemorrhage on two occasions
- retained placenta on two occasions
- puerperal psychosis
- grand multiparity (more than six pregnancies)
- a stillbirth or neonatal death
- a small-for-gestational-age infant (less than fifth centile)
- a large-for-gestational-age infant (greater than 95th centile)
- a baby weighing less than 2500 g or more than 4500 g
- a baby with a congenital anomaly (structural or chromosomal).

KEY RECOMMENDATIONS

- Pregnant women should be offered evidence-based information and support to enable them to make informed decisions regarding their care. Information should include details of where they will be seen and who will undertake their care. Addressing women's choices should be recognised as being integral to the decision-making process.
- A schedule of antenatal appointments should be determined by the function of the appointments. For a woman who is nulliparous with an uncomplicated pregnancy, a schedule of 10 appointments should be adequate. For a woman who is parous with an uncomplicated pregnancy, a schedule of seven appointments should be adequate.
- Pregnant women should be offered an early ultrasound scan to determine gestational age (in lieu of last menstrual period [LMP] for all cases) and to detect multiple

pregnancies. This will ensure consistency of gestational age assessments, improve the performance of mid-trimester serum screening for Down's syndrome and reduce the need for induction of labour after 41 weeks.

- Pregnant women should be offered screening for Down's syndrome with a test which provides the current standard of a detection rate above 60% and a false-positive rate of less than 5%. The following tests meet this standard:
  - from 11 to 14 weeks
    - nuchal translucency (NT)
    - the combined test (NT, hCG and PAPP-A)
  - from 14 to 20 weeks
    - the triple test (hCG, AFP and uE3)
    - the quadruple test (hCG, AFP, uE3, inhibin A)
  - from 11 to 14 weeks and 14 to 20 weeks
    - the integrated test (NT, PAPP-A + hCG, AFP, uE3, inhibin A)
    - the serum integrated test (PAPP-A + hCG, AFP, uE3, inhibin A).
- The evidence does not support routine screening for gestational diabetes mellitus and therefore it should not be offered.

GUIDANCE

Woman-centred care and informed decision making

The principles outlined in this section apply to all aspects of the antenatal care guideline.

- Pregnant women should be offered opportunities to attend antenatal classes and have written information about antenatal care.Ⓐ
- Pregnant women should be offered evidence-based information and support to enable them to make informed decisions regarding their care. Information should include details of where they will be seen and who will undertake their care. Addressing women's choices should be recognised as being integral to the decision-making process.Ⓒ

- At the first contact, pregnant women should be offered information about: the pregnancy-care services and options available; lifestyle considerations, including dietary information; and screening tests. Ⓒ
- Pregnant women should be informed about the purpose of any screening test before it is performed. The right of a woman to accept or decline a test should be made clear. Ⓓ
- At each antenatal appointment, midwives and doctors should offer consistent information and clear explanations, and should provide pregnant women with an opportunity to discuss issues and ask questions. Ⓓ
- Communication and information should be provided in a form that is accessible to pregnant women who have additional needs, such as those with physical, cognitive, or sensory disabilities and those who do not speak or read English. GPP

Please note that all first-time pregnant women in England and Wales should be offered *The Pregnancy Book* (published by health departments in England and Wales) by their carer. This book provides information on many aspects of pregnancy including: how the fetus develops; deciding where to have a baby; feelings and relationships during pregnancy; antenatal care and classes; problems in pregnancy; when pregnancy goes wrong; rights and benefits information; and a list of useful organisations. It also has a section for expectant fathers.

Provision and organisation of care

WHO PROVIDES CARE?

- Midwife- and GP-led models of care should be offered for women with an uncomplicated pregnancy. Routine involvement of obstetricians in the care of women with an uncomplicated pregnancy at scheduled times does not appear to improve perinatal outcomes compared with involving obstetricians when complications arise. Ⓐ

CONTINUITY OF CARE

- Antenatal care should be provided by a small group of carers with whom the woman feels comfortable. There should be continuity of care throughout the antenatal period.Ⓐ

- A system of clear referral paths should be established so that pregnant women who require additional care are managed and treated by the appropriate specialist teams when problems are identified.Ⓓ

WHERE SHOULD ANTENATAL APPOINTMENTS TAKE PLACE?

- Antenatal care should be readily and easily accessible to all women and should be sensitive to the needs of individual women and the local community.Ⓒ
- The environment in which antenatal appointments take place should enable women to discuss sensitive issues such as domestic violence, sexual abuse, psychiatric illness and illicit drug use. GPP

DOCUMENTATION OF CARE

- Structured maternity records should be used for antenatal care.Ⓐ
- Maternity services should have a system in place whereby women carry their own case notes. Ⓐ
- A standardised, national maternity record with an agreed minimum data set should be developed and used. This will help carers to provide the recommended evidence-based care to pregnant women. GPP

FREQUENCY OF ANTENATAL APPOINTMENTS

- A schedule of antenatal appointments should be determined by the function of the appointments. For a woman who is nulliparous with an uncomplicated pregnancy, a schedule of ten appointments should be adequate. For a woman who is parous with an uncomplicated pregnancy, a schedule of seven appointments should be adequate.Ⓑ
- Early in pregnancy all women should receive appropriate written information about the likely number, timing and content of antenatal appointments associated with different options of care and be given an opportunity to discuss this schedule with their midwife or doctor.Ⓓ
- Each antenatal appointment should be structured and have

focused content. Longer appointments are needed early in pregnancy to allow comprehensive assessment and discussion. Wherever possible, appointments should incorporate routine tests and investigations to minimise inconvenience to women.Ⓓ

GESTATIONAL AGE ASSESSMENT: LMP AND ULTRASOUND

- Pregnant women should be offered an early ultrasound scan to determine gestational age (in lieu of last menstrual period [LMP] for all cases) and to detect multiple pregnancies. This will ensure consistency of gestational age assessments, improve the performance of mid-trimester serum screening for Down's syndrome and reduce the need for induction of labour after 41 weeks.Ⓐ
- Ideally, scans should be performed between 10 and 13 weeks and crown–rump length measurement used to determine gestational age. Pregnant women who present at or beyond 14 weeks' gestation should be offered an ultrasound scan to estimate gestational age using head circumference or bi-parietal diameter. GPP

WHAT SHOULD HAPPEN AT ANTENATAL APPOINTMENTS?

The content of the first appointment, and of appointments at 16, 18–20, 25, 28, 31, 34, 36, 38, 40 and 41 weeks is listed in Table 2.

Table 2 Antenatal appointments (schedule and content)

The schedule below, which has been determined by the purpose of each appointment, presents the recommended number of antenatal care appointments for women who are healthy and whose pregnancies remain uncomplicated in the antenatal period: ten appointments for nulliparous women and seven for parous women.

First appointment(s)

The first appointment needs to be earlier in pregnancy (prior to 12 weeks) than may have traditionally occurred and, because of the large volume of information needs in early pregnancy, two appointments may be required. At the first (and second) antenatal appointment:

- give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by written information (on topics such as diet and lifestyle considerations, pregnancy care services available, maternity benefits and sufficient information to enable informed decision making about screening tests)

- identify women who may need additional care (see Appendix E) and plan pattern of care for the pregnancy
- check blood group and RhD status
- offer screening for anaemia, red-cell alloantibodies, hepatitis B virus, HIV, rubella susceptibility and syphilis
- offer screening for asymptomatic bacteriuria
- offering screening for Down's syndrome
- offer early ultrasound scan for gestational age assessment
- offer ultrasound screening for structural anomalies (20 weeks)
- measure BMI, blood pressure and test urine for proteinuria.

After the first (and possibly second) appointment, for women who choose to have screening, the following test should be arranged before 16 weeks of gestation (except serum screening for Down's syndrome, which may occur at up to 20 weeks of gestation):

- blood tests (for checking blood group and RhD status and screening for anaemia, red-cell alloantibodies, hepatitis B virus, HIV, rubella susceptibility and syphilis)
- urine tests (to check for proteinuria and screen for asymptomatic bacteriuria)
- ultrasound scan to determine gestational age using:
  - crown–rump measurement if performed at 10 to 13 weeks
  - bi-parietal diameter or head circumference at or beyond 14 weeks
- Down's syndrome screening using:
  - nuchal translucency at 11 to 14 weeks
  - serum screening at 14 to 20 weeks.

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16 weeks

The next appointment should be scheduled at 16 weeks to:

- review, discuss and document the results of all screening tests undertaken; reassess planned pattern of care for the pregnancy and identify women who need additional care (see Table 1)
- investigate a haemoglobin level of less than 11 g/dl and consider iron supplementation if indicated

- measure blood pressure and test urine for proteinuria
- give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information.

18–20 weeks

At 18–20 weeks, if the woman chooses, an ultrasound scan should be performed for the detection of structural anomalies. For a woman whose placenta is found to extend across the internal cervical os at this time, another scan at 36 weeks should be offered and the results of this scan reviewed at the 36-week appointment.

25 weeks

At 25 weeks of gestation, another appointment should be scheduled for nulliparous women. At this appointment:

- measure and plot symphysis–fundal height
- measure blood pressure and test urine for proteinuria
- give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information.

28 weeks

The next appointment for all pregnant women should occur at 28 weeks. At this appointment:

- offer a second screening for anaemia and atypical red-cell alloantibodies
- investigate a haemoglobin level of less than 10.5 g/100 ml and consider iron supplementation, if indicated
- offer anti-D to rhesus-negative women
- measure blood pressure and test urine for proteinuria
- measure and plot symphysis–fundal height
- give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information.

31 weeks

Nulliparous women should have an appointment scheduled at 31 weeks to:

- measure blood pressure and test urine for proteinuria

- measure and plot symphysis–fundal height
- give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information
- review, discuss and document the results of screening tests undertaken at 28 weeks; reassess planned pattern of care for the pregnancy and identify women who need additional care (see Table 1).

34 weeks

At 34 weeks, all pregnant women should be seen in order to:

- offer a second dose of anti-D to rhesus-negative women
- measure blood pressure and test urine for proteinuria
- measure and plot symphysis–fundal height
- give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information
- review, discuss and document the results of screening tests undertaken at 28 weeks; reassess planned pattern of care for the pregnancy and identify women who need additional care (see Table 1).

36 weeks

At 36 weeks, all pregnant women should be seen again to:

- measure blood pressure and test urine for proteinuria
- measure and plot symphysis–fundal height
- check position of baby
- for women whose babies are in the breech presentation, offer external cephalic version
- review ultrasound scan report if placenta extended over the internal cervical os at previous scan
- give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information.

38 weeks

Another appointment at 38 weeks will allow for:

- measurement of blood pressure and urine testing for proteinuria
- measurement and plotting of symphysis–fundal height

- information giving, with an opportunity to discuss issues and ask questions; verbal information supported by antenatal classes and written information.

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40 weeks

For nulliparous women, an appointment at 40 weeks should be scheduled to:

- measure blood pressure and test urine for proteinuria
- measure and plot symphysis–fundal height
- give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information.

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41 weeks

For women who have not given birth by 41 weeks:

- a membrane sweep should be offered
- induction of labour should be offered
- blood pressure should be measured and urine tested for proteinuria
- symphysis–fundal height should be measured and plotted
- information should be given, with an opportunity to discuss issues and ask questions; verbal information supported by written information.

General

Throughout the entire antenatal period, healthcare providers should remain alert to signs or symptoms of conditions which affect the health of the mother and fetus, such as domestic violence, pre-eclampsia and diabetes.

Lifestyle considerations

WORKING DURING PREGNANCY

- Pregnant women should be informed of their maternity rights and benefits.Ⓒ
- The majority of women can be reassured that it is safe to continue working during pregnancy. Further information about possible occupational hazards during pregnancy is available from the Health and Safety Executive (www.hse.gov.uk/mothers/index.htm).Ⓓ
- A woman's occupation during pregnancy should be

ascertained to identify those at increased risk through occupational exposure. GPP

Information on maternity rights and benefits often changes with time. Further information may be obtained from the Department of Trade and Industry (DTI) website (www.dti.gov.uk/er/workingparents.htm or call 0870 1502 500 for information leaflets) or the Government's interactive guidance site (www.tiger.gov.uk). Up-to-date information on maternity benefits can also be accessed at the Department for Work and Pensions (www.dwp.gov.uk).

NUTRITIONAL SUPPLEMENTS

- Pregnant women (and those intending to become pregnant) should be informed that dietary supplementation with folic acid, before conception and up to 12 weeks' gestation, reduces the risk of having a baby with neural tube defects (anencephaly, spina bifida). The recommended dose is 400 micrograms per day.Ⓐ
- Iron supplementation should not be offered routinely to all pregnant women. It does not benefit the mother's or fetus's health and may have unpleasant maternal side effects.Ⓐ
- Pregnant women should be informed that vitamin A supplementation (intake greater than 700 micrograms) might be teratogenic and therefore it should be avoided. Pregnant women should be informed that as liver and liver products may also contain high levels of vitamin A, consumption of these products should also be avoided.Ⓒ
- There is insufficient evidence to evaluate the effectiveness of vitamin D in pregnancy. In the absence of evidence of benefit, vitamin D supplementation should not be offered routinely to pregnant women.Ⓐ

FOOD-ACQUIRED INFECTIONS

- Pregnant women should be offered information on how to reduce the risk of listeriosis by:
  - drinking only pasteurised or UHT milk
  - not eating ripened soft cheese such as Camembert, Brie, and blue-veined cheese (there is no risk with hard cheeses

such as cheddar, or cottage cheese and processed cheese)

  - not eating pate (of any sort, including vegetable)
  - not eating uncooked or undercooked ready-prepared meals.Ⓓ

- Pregnant women should be offered information on how to reduce the risk of salmonella infection by:
  - avoiding raw or partially cooked eggs or food that may contain them (such as mayonnaise)
  - avoiding raw or partially cooked meat, especially poultry.Ⓓ

PRESCRIBED MEDICINES

- Few medicines have been established as safe to use in pregnancy. Prescription medicines should be used as little as possible during pregnancy and should be limited to circumstances where the benefit outweighs the risk.Ⓓ

OVER-THE-COUNTER MEDICINES

- Pregnant women should be informed that few over-the-counter (OTC) medicines have been established as being safe to take in pregnancy. OTC medicines should be used as little as possible during pregnancy.Ⓓ

COMPLEMENTARY THERAPIES

- Pregnant women should be informed that few complementary therapies have been established as being safe and effective during pregnancy. Women should not assume that such therapies are safe and they should be used as little as possible during pregnancy.Ⓓ

EXERCISE IN PREGNANCY

- Pregnant women should be informed that beginning or continuing a moderate course of exercise during pregnancy is not associated with adverse outcomes.Ⓐ
- Pregnant women should be informed of the potential dangers of certain activities during pregnancy, for example, contact sports, high-impact sports and vigorous racquet sports that may involve the risk of abdominal trauma, falls

or excessive joint stress, and scuba diving, which may result in fetal birth defects and fetal decompression disease.Ⓓ

SEXUAL INTERCOURSE IN PREGNANCY

- Pregnant woman should be informed that sexual intercourse in pregnancy is not known to be associated with any adverse outcomes.Ⓑ

ALCOHOL AND SMOKING IN PREGNANCY

- Excess alcohol has an adverse effect on the fetus. Therefore it is suggested that women limit alcohol consumption to no more than one standard unit per day. Each of the following constitutes one 'unit' of alcohol: a single measure of spirits, one small glass of wine, and a half pint of ordinary strength beer, lager or cider.Ⓒ
- Pregnant women should be informed about the specific risks of smoking during pregnancy (such as the risk of having a baby with low birth weight and preterm). The benefits of quitting at any stage should be emphasised.Ⓐ
- Women who smoke or who have recently stopped should be offered smoking cessation interventions. Interventions that appear to be effective in reducing smoking include advice by physician, group sessions, and behavioural therapy (based on self-help manuals).Ⓐ
- Women who are unable to quit smoking during pregnancy should be encouraged to reduce smoking.Ⓑ

The NHS pregnancy smoking helpline is available at 0800 169 0 169.

CANNABIS USE IN PREGNANCY

- The direct effects of cannabis on the fetus are uncertain but may be harmful. Cannabis use is associated with smoking, which is known to be harmful; therefore, women should be discouraged from using cannabis during pregnancy.Ⓒ

AIR TRAVEL DURING PREGNANCY

- Pregnant women should be informed that long-haul air travel is associated with an increased risk of venous thrombosis, although whether or not there is additional risk during pregnancy is unclear. In the general population, wearing correctly fitted compression stockings is effective at reducing the risk. Ⓑ

CAR TRAVEL DURING PREGNANCY

- Pregnant women should be informed about the correct use of seat belts (that is, three-point seatbelts 'above and below the bump, not over it'). Ⓑ

TRAVELLING ABROAD DURING PREGNANCY

- Pregnant women should be informed that, if they are planning to travel abroad, they should discuss considerations such as flying, vaccinations and travel insurance with their midwife or doctor. GPP

Management of common symptoms of pregnancy

NAUSEA AND VOMITING IN EARLY PREGNANCY

- Women should be informed that most cases of nausea and vomiting in pregnancy will resolve spontaneously within 16 to 20 weeks of gestation and that nausea and vomiting are not usually associated with a poor pregnancy outcome. If a woman requests or would like to consider treatment, the following interventions appear to be effective in reducing symptoms:
  - non-pharmacological
    - ○ ginger
    - ○ P6 acupressure
  - pharmacological
    - ○ antihistamines. Ⓐ
- Information about all forms of self-help and non-pharmacological treatments should be made available for pregnant women who have nausea and vomiting. GPP

HEARTBURN

- Women who present with symptoms of heartburn in pregnancy should be offered information regarding lifestyle and diet modification. GPP
- Antacids may be offered to women whose heartburn

remains troublesome despite lifestyle and diet modification.Ⓐ

CONSTIPATION

- Women who present with constipation in pregnancy should be offered information regarding diet modification, such as bran or wheat fibre supplementation.Ⓐ

HAEMORRHOIDS

- In the absence of evidence of the effectiveness of treatments for haemorrhoids in pregnancy, women should be offered information concerning diet modification. If clinical symptoms remain troublesome, standard haemorrhoid creams should be considered. GPP

VARICOSE VEINS

- Women should be informed that varicose veins are a common symptom of pregnancy that will not cause harm and that compression stockings can improve the symptoms but will not prevent varicose veins from emerging.Ⓐ

VAGINAL DISCHARGE

- Women should be informed that an increase in vaginal discharge is a common physiological change that occurs during pregnancy. If this is associated with itch, soreness, offensive smell or pain on passing urine there may be an infective cause and investigation should be considered. GPP
- A 1-week course of a topical imidazole is an effective treatment and should be considered for vaginal candidiasis infections in pregnant women.Ⓐ
- The effectiveness and safety of oral treatments for vaginal candidiasis in pregnancy is uncertain and these should not be offered. GPP

BACKACHE

- Women should be informed that exercising in water, massage therapy and group or individual back care classes might help to ease backache during pregnancy.Ⓐ

Clinical examination of pregnant women

MEASUREMENT OF WEIGHT AND BODY MASS INDEX (BMI)

- Maternal weight and height should be measured at the first antenatal appointment, and the woman's BMI calculated (weight [kg]/height[m]^2).Ⓑ
- Repeated weighing during pregnancy should be confined to circumstances where clinical management is likely to be influenced.Ⓒ

BREAST EXAMINATION

- Routine breast examination during antenatal care is not recommended for the promotion of postnatal breastfeeding.Ⓐ

PELVIC EXAMINATION

- Routine antenatal pelvic examination does not accurately assess gestational age, nor does it accurately predict preterm birth or cephalopelvic disproportion. It is not recommended.Ⓑ

FEMALE GENITAL MUTILATION

- Pregnant women who have had female genital mutilation should be identified early in antenatal care through sensitive enquiry. Antenatal examination will then allow planning of intrapartum care.Ⓒ

DOMESTIC VIOLENCE

- Healthcare professionals need to be alert to the symptoms or signs of domestic violence and women should be given the opportunity to disclose domestic violence in an environment in which they feel secure.Ⓓ

Further information on domestic violence is offered in the Department of Health Publication *Domestic Violence: A Resource Manual for Health Care Professionals* (March 2000).

PSYCHIATRIC SCREENING

- Women should be asked early in pregnancy if they have had any previous psychiatric illnesses. Women who have had a past history of serious psychiatric disorder should be referred for a psychiatric assessment during the antenatal period.Ⓑ

- Pregnant women should not be offered routine screening, such as with the Edinburgh postnatal depression scale (EPDS), in the antenatal period to predict the development of postnatal depression.Ⓐ
- Pregnant women should not be offered antenatal education interventions to reduce perinatal or postnatal depression, as these interventions have not been shown to be effective.Ⓐ

Screening for haematological conditions

ANAEMIA

- Pregnant women should be offered screening for anaemia. Screening should take place early in pregnancy (at the first appointment) and at 28 weeks when other blood screening tests are being performed. This allows enough time for treatment if anaemia is detected.Ⓑ
- Haemoglobin levels outside the normal UK range for pregnancy (that is, 11 g/dl at first contact and 10.5 g/dl at 28 weeks) should be investigated and iron supplementation considered if indicated.Ⓐ

BLOOD GROUPING AND RED CELL ALLOANTIBODIES

- Women should be offered testing for blood group and RhD status in early pregnancy.Ⓑ
- It is recommended that routine antenatal anti-D prophylaxis is offered to all non-sensitised pregnant women who are RhD negative. NICE 2002
- Women should be screened for atypical red cell alloantibodies in early pregnancy and again at 28 weeks regardless of their RhD status.Ⓑ
- Pregnant women with clinically significant atypical red cell alloantibodies should be offered referral to a specialist centre for further investigation and advice on subsequent antenatal management.Ⓓ
- If a pregnant woman is RhD-negative, consideration should be given to offering partner testing to determine

whether the administration of anti-D prophylaxis is necessary. GPP

Screening for fetal anomalies

SCREENING FOR STRUCTURAL ANOMALIES

- Pregnant women should be offered an ultrasound scan to screen for structural anomalies, ideally between 18 and 20 weeks' gestation, by an appropriately trained sonographer and with equipment of an appropriate standard as outlined by the National Screening Committee. Ⓐ

SCREENING FOR DOWN'S SYNDROME

- Pregnant women should be offered screening for Down's syndrome with a test which provides the current standard of a detection rate above 60% and a false-positive rate of less than 5%. The following tests meet this standard:
  - from 11 to 14 weeks
    - ○ nuchal translucency (NT)
    - ○ the combined test (NT, hCG and PAPP-A)
  - from 14 to 20 weeks
    - ○ the triple test (hCG, AFP and uE3)
    - ○ the quadruple test (hCG, AFP, uE3, inhibin A)
  - from 11 to 14 weeks **and** 14 to 20 weeks
    - ○ the integrated test (NT, PAPP-A + hCG, AFP, uE3, inhibin A)
    - ○ the serum integrated test (PAPP-A + hCG, AFP, uE3, inhibin A). Ⓑ
- By April 2007, pregnant women should be offered screening for Down's syndrome with a test which provides a detection rate above 75% and a false-positive rate of less than 3%. These performance measures should be age-standardised and based on a cutoff of 1 in 250 at term. The following tests currently meet this standard:
  - from 11 to 14 weeks
    - ○ the combined test (NT, hCG and PAPP-A)
  - from 14 to 20 weeks

    - ○ the quadruple test (hCG, AFP, uE3, inhibin A)
  - – from 11 to 14 weeks **and** 14 to 20 weeks
    - ○ the integrated test (NT, PAPP-A + hCG, AFP, uE3, inhibin A)
    - ○ the serum integrated test (PAPP-A + hCG, AFP, uE3, inhibin A).Ⓑ

- Pregnant women should be given information about the detection rates and false-positive rates of any Down's syndrome screening test being offered and about further diagnostic tests that may be offered. The woman's right to accept or decline the test should be made clear.Ⓓ

Screening for infections

ASYMPTOMATIC BACTERIURIA

- Pregnant women should be offered routine screening for asymptomatic bacteriuria by midstream urine culture early in pregnancy. Identification and treatment of asymptomatic bacteriuria reduces the risk of preterm birth.Ⓐ

ASYMPTOMATIC BACTERIAL VAGINOSIS

- Pregnant women should not be offered routine screening for bacterial vaginosis because the evidence suggests that the identification and treatment of asymptomatic bacterial vaginosis does not lower the risk for preterm birth and other adverse reproductive outcomes.Ⓐ

CHLAMYDIA TRACHOMATIS

- Pregnant women should not be offered routine screening for asymptomatic chlamydia because there is insufficient evidence on its effectiveness and cost effectiveness. However, this policy is likely to change with the implementation of the national opportunistic chlamydia screening programme.Ⓒ

CYTOMEGALOVIRUS

- The available evidence does not support routine cytomegalovirus screening in pregnant women and it should not be offered.Ⓑ

HEPATITIS B VIRUS

- Serological screening for hepatitis B virus should be offered to pregnant women so that effective postnatal intervention can be offered to infected women to decrease the risk of mother-to-child transmission.Ⓐ

HEPATITIS C VIRUS

- Pregnant women should not be offered routine screening for hepatitis C virus because there is insufficient evidence on its effectiveness and cost effectiveness.Ⓒ

HIV

- Pregnant women should be offered screening for HIV infection early in antenatal care because appropriate antenatal interventions can reduce mother-to-child transmission of HIV infection.Ⓐ
- A system of clear referral paths should be established in each unit or department so that pregnant women who are diagnosed with an HIV infection are managed and treated by the appropriate specialist teams.Ⓓ

RUBELLA

- Rubella-susceptibility screening should be offered early in antenatal care to identify women at risk of contracting rubella infection and to enable vaccination in the postnatal period for the protection of future pregnancies.Ⓑ

STREPTOCOCCUS GROUP B

- Pregnant women should not be offered routine antenatal screening for group B streptococcus (GBS) because evidence of its clinical effectiveness and cost effectiveness remains uncertain.Ⓒ

SYPHILIS

- Screening for syphilis should be offered to all pregnant women at an early stage in antenatal care because treatment of syphilis is beneficial to the mother and fetus.Ⓑ
- Because syphilis is a rare condition in the UK and a positive result does not necessarily mean that a woman has syphilis,

clear paths of referral for the management of women testing positive for syphilis should be established. GPP

TOXOPLASMOSIS

- Routine antenatal serological screening for toxoplasmosis should not be offered because the harms of screening may outweigh the potential benefits.Ⓑ
- Pregnant women should be informed of primary prevention measures to avoid toxoplasmosis infection, such as:
  - washing hands before handling food
  - thoroughly washing all fruit and vegetables, including ready-prepared salads, before eating
  - thoroughly cooking raw meats and ready-prepared chilled meals
  - wearing gloves and thoroughly washing hands after handling soil and gardening
  - avoiding cat faeces in cat litter or in soil.Ⓒ

Screening for clinical conditions

GESTATIONAL DIABETES MELLITUS

- The evidence does not support routine screening for gestational diabetes mellitus and therefore it should not be offered.Ⓑ

PRE-ECLAMPSIA

- At first contact a woman's level of risk for pre-eclampsia should be evaluated so that a plan for her subsequent schedule of antenatal appointments can be formulated. The likelihood of developing pre-eclampsia during a pregnancy is increased in women who:
  - are nulliparous
  - are aged 40 or older
  - have a family history of pre-eclampsia (for example, pre-eclampsia in a mother or sister)
  - have a prior history of pre-eclampsia

  - have a body mass index (BMI) at or above 35 at first contact
  - have a multiple pregnancy or pre-existing vascular disease (for example, hypertension or diabetes).Ⓒ

- Whenever blood pressure is measured in pregnancy a urine sample should be tested at the same time for proteinuria.Ⓒ
- Standardised equipment, techniques and conditions for blood-pressure measurement should be used by all personnel whenever blood pressure is measured in the antenatal period so that valid comparisons can be made.Ⓒ
- Pregnant women should be informed of the symptoms of advanced pre-eclampsia because these may be associated with poorer pregnancy outcomes for the mother or baby. Symptoms include headache; problems with vision, such as blurring or flashing before the eyes; bad pain just below the ribs; vomiting and sudden swelling of face, hands or feet.Ⓓ

PRETERM BIRTH

- Routine vaginal examinations to assess the cervix is not an effective method of predicting preterm birth and should not be offered.Ⓐ
- Although cervical shortening identified by transvaginal ultrasound examination and increased levels of fetal fibronectin are associated with an increased risk for preterm birth, the evidence does not indicate that this information improves outcomes; therefore, neither routine antenatal cervical assessment by transvaginal ultrasound nor the measurement of fetal fibronectin should be used to predict preterm birth in healthy pregnant women.Ⓑ

PLACENTA PRAEVIA

- Because most low-lying placentas detected at a 20-week anomaly scan will resolve by the time the baby is born, only a woman whose placenta extends over the internal cervical os should be offered another transabdominal scan at 36 weeks. If the transabdominal scan is unclear, a transvaginal scan should be offered.Ⓒ

Fetal growth and well-being

ABDOMINAL PALPATION FOR FETAL PRESENTATION

- Fetal presentation should be assessed by abdominal palpation at 36 weeks or later, when presentation is likely to influence the plans for the birth. Routine assessment of presentation by abdominal palpation should not be offered before 36 weeks because it is not always accurate and may be uncomfortable.Ⓒ
- Suspected fetal malpresentation should be confirmed by an ultrasound assessment. GPP

MEASUREMENT OF SYMPHYSIS–FUNDAL DISTANCE

- Pregnant women should be offered estimation of fetal size at each antenatal appointment to detect small- or large-for-gestational-age infants.Ⓐ
- Symphysis–fundal height should be measured and plotted at each antenatal appointment. GPP

ROUTINE MONITORING OF FETAL MOVEMENTS

- Routine formal fetal-movement counting should not be offered.Ⓐ

AUSCULTATION OF FETAL HEART

- Auscultation of the fetal heart may confirm that the fetus is alive but is unlikely to have any predictive value and routine listening is therefore not recommended. However, when requested by the mother, auscultation of the fetal heart may provide reassurance.Ⓓ

CARDIOTOCOGRAPHY

- The evidence does not support the routine use of antenatal electronic fetal heart rate monitoring (cardiotocography) for fetal assessment in women with an uncomplicated pregnancy and therefore it should not be offered.Ⓐ

ULTRASOUND ASSESSMENT IN THE THIRD TRIMESTER

- The evidence does not support the routine use of ultrasound scanning after 24 weeks' gestation and therefore it should not be offered.Ⓐ

UMBILICAL AND UTERINE ARTERY DOPPLER ULTRASOUND

- The use of umbilical artery Doppler ultrasound for the prediction of fetal growth restriction should not be offered routinely. Ⓐ
- The use of uterine artery Doppler ultrasound for the prediction of pre-eclampsia should not be offered routinely. Ⓑ

Management of specific clinical conditions

PREGNANCY AFTER 41 WEEKS

(See also 'Gestational age assessment: LMP and ultrasound' above.)

- Prior to formal induction of labour, women should be offered a vaginal examination for membrane sweeping. Ⓐ
- Women with uncomplicated pregnancies should be offered induction of labour beyond 41 weeks. Ⓐ
- From 42 weeks, women who decline induction of labour should be offered increased antenatal monitoring consisting of at least twice-weekly cardiotocography and ultrasound estimation of maximum amniotic pool depth. GPP

BREECH PRESENTATION AT TERM

- All women who have an uncomplicated singleton breech pregnancy at 36 weeks' gestation should be offered external cephalic version (ECV). Exceptions include women in labour, and women with: a uterine scar or abnormality; fetal compromise; ruptured membranes; vaginal bleeding and medical conditions. Ⓐ

Where it is not possible to schedule an appointment for ECV at 37 weeks' gestation, it should be scheduled at 36 weeks. GPP

INTERVENTIONAL PROCEDURE

Balloon thermal endometrial ablation

Issue date – August 2003

Current evidence on the safety and efficacy of balloon thermal endometrial ablation appears adequate to support the use of this procedure, provided that the normal arrangements for consent, audit and clinical governance are in place.

It is recommended that the Medical Devices Agency safety notices on endometrial ablation are followed (MDA [1998] SN 9812 *Devices used for endometrial ablation achieved by thermal means*, and MDA [1999] SN 1999(18) *Devices used for endometrial ablation*, available from www.medical-devices.gov.uk).*

* In 1998 and 1999 the Medical Devices Agency (which became the Medicines and Healthcare products Regulatory Agency [MHRA] in April 2003) made the following recommendations.

- Clinicians should carefully consider the use of thermal endometrial ablation in the following circumstances:
  - a small (thin-walled) uterus
  - pre-operative hormone treatments, or
  - a history of pelvic infections (for example, where fibrosis and bowel adhesions are more likely to be present).
- In cases of suspected uterine displacement clinicians should verify the correct placement using ultrasound before the device is activated.
- The concurrent use of diathermy during such procedures should not be undertaken due to the risk of the ablation device as a source of alternate site burns.

The US Food and Drug Administration (FDA) recently issued similar recommendations.

Electronic fetal monitoring

Issue date – May 2001 **Review date** – January 2003

EVIDENCE LEVELS

The definitions of the types of evidence used in this guideline originate from the US Agency for Health Care Policy and Research.

Levels of evidence

Level	Type of evidence
Ia	Evidence obtained from systematic review of meta-analysis of randomised controlled trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Note: A Clinical Practice Algorithmn is available from the NICE website www.nice.org.uk.

The grading scheme used was based on a scheme formulated by the Clinical Outcomes Group (COG) of the NHS Executive.

Grading of recommendations

Grade	Requirements
Ⓐ	Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)
Ⓑ	Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of the recommendation (evidence levels IIa, IIb, III)
Ⓒ	Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

Good practice points

✔ Recommended good practice based on the clinical experience of the Guideline Development Group.

For this guideline, electronic fetal monitoring (EFM) is defined as ‘the use of electronic fetal heart-rate monitoring for the evaluation of fetal wellbeing in labour’.

EFM was introduced with an aim of reducing perinatal mortality and cerebral palsy. This reduction has not been demonstrated in the systematic reviews of randomised controlled trials (RCTs). However an increase in maternal intervention rates has been shown.

Indications for the use of continuous EFM

There are a number of antenatal and intrapartum risk factors that have been shown to be associated with the development of neonatal encephalopathy, cerebral palsy or even perinatal death.

Continuous EFM should be offered and recommended for high-risk pregnancies where there is an increased risk of perinatal death, cerebral palsy or neonatal encephalopathy.Ⓑ

Continuous EFM should be used where oxytocin is being used for induction or augmentation of labour.Ⓒ

Care of women

The assessment of fetal wellbeing is only one component of intrapartum care. It is an important area where due consideration must be given to maternal preference and priorities in the light of potential risk factors to both mother and baby, i.e. one that strikes the right balance between the objective of maximising the detection of potentially compromised babies and the objective of minimising the number of unnecessary maternal interventions. The provision of accurate information in these circumstances is essential to allow each woman to make the right decision for her.

Women must be able to make informed choices regarding their care or treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.Ⓒ

Women should have the same level of care and support regardless of the mode of intrapartum fetal monitoring.Ⓒ

Trusts should ensure that there are clear lines of communication between carers and consistent terminology is used to convey urgency or concern regarding fetal wellbeing.Ⓒ

Prior to any form of fetal monitoring, the maternal pulse should be palpated simultaneously with fetal heart-rate auscultation in order to differentiate between maternal and fetal heart rates.Ⓒ

If fetal death is suspected despite the presence of an apparently recorded fetal heart rate (FHR), then fetal viability should be confirmed with real-time ultrasound assessment.Ⓒ

With regard to the use of intermittent auscultation:Ⓒ

- The FHR should be auscultated at specified intervals (see 'Appropriate monitoring in an uncomplicated pregnancy' below).
- Any intrapartum events that may affect the FHR should be noted contemporaneously in the maternal notes, signed and the time noted.

With regard to the use of EFM:Ⓒ

- The date and time clocks on the EFM machine should be correctly set.
- Traces should be labelled with the mother's name, date and hospital number.
- Any intrapartum events that may affect the FHR should be noted contemporaneously on the EFM trace, signed and the date and time noted (e.g. vaginal examination, fetal blood sample, siting of an epidural).
- Any member of staff who is asked to provide an opinion on a trace should note their findings on both the trace and maternal case notes along with date, time and signature.
- Following birth, the caregiver should sign and note the date, time and mode of birth on the EFM trace.
- The EFM trace should be stored securely with the maternal notes at the end of the monitoring process.

Appropriate monitoring in an uncomplicated pregnancy

For a woman who is healthy and has had an otherwise uncomplicated pregnancy, intermittent auscultation should be offered and recommended in labour to monitor fetal wellbeing. Ⓐ

In the active stages of labour, intermittent auscultation should occur after a contraction, for a minimum of 60 seconds, and at least: Ⓐ

- Every 15 minutes in the first stage.
- Every 5 minutes in the second stage.

Continuous EFM should be offered and recommended in pregnancies previously monitored with intermittent auscultation: Ⓐ

- If there is evidence on auscultation of a baseline less than 110 or greater than 160 bpm.
- If there is evidence on auscultation of any decelerations.
- If any intrapartum risk factors develop.

Current evidence does not support the use of the admission cardiotocography (CTG) in low-risk pregnancy and it is therefore not recommended. Ⓑ

Interpretation of EFM

Interpretation of EFM traces requires a definition of what is normal. The definition of normal should be derived by the identification of cases where values outside a given range increase the likelihood of the adverse outcomes identified above. The definitions and descriptions of individual features of FHR traces shown in the tables below are used in the Guideline and in the Clinical Practice Algorithm.

Categorisation of fetal heart rate traces

Category	Definition
Normal	A CTG where all four features fall into the reassuring category.
Suspicious	A CTG whose features fall into one of the non-reassuring categories and the remainder of the features are reassuring.
Pathological	A CTG whose features fall into two or more non-reassuring categories or one or more abnormal categories.

Categorisation of fetal heart rate (FHR) features

Feature	Baseline (bpm)	Variability (bpm)	Decelerations	Accelerations
Reassuring	110–160	≥ 5	None	Present
Non-reassuring	100–109 161–180	< 5 for ≥ 40 to <90 minutes	Early deceleration Variable deceleration Single prolonged deceleration up to 3 minutes	*The absence of accelerations with an otherwise normal cardiotocograph are of uncertain significance*
Abnormal	<100 >180 Sinusoidal pattern ≥ 10 minutes	<5 for ≥ 90 minutes	Atypical variable decelerations Late decelerations Single prolonged deceleration >3 minutes	

A grading system for FHR patterns is recommended. This incorporates both the proposed definitions of FHR patterns and categorisation schemes.✓

- In cases where the CTG falls into the suspicious category, conservative measures should be used.
- In cases where the CTG falls into the pathological category, conservative measures should be used and fetal blood sampling be undertaken where appropriate/feasible. In situations where fetal blood sampling is not possible or appropriate then delivery should be expedited.
- For an outline of conservative measures please refer to the Clinical Practice Algorithm.

Settings on CTG machines should be standardised, so that: ✓

- Paper speed is set to 1 centimetre (cm) per minute.

- Sensitivity displays are set to 20 beats per minute (bpm)/cm.
- FHR range displays of 50–210 bpm are used.

Additional tests and therapies used in combination with EFM

Units employing EFM should have ready access to fetal blood sampling facilities.Ⓐ

Where delivery is contemplated because of an abnormal fetal heart-rate pattern, in cases of suspected fetal acidosis, fetal blood sampling should be undertaken in the absence of technical difficulties or contraindications.Ⓐ

Fetal blood sampling should be undertaken with the mother in the left-lateral position.Ⓑ

Contraindications to fetal blood sampling include:Ⓑ

- Maternal infection (e.g. HIV, hepatitis viruses and herpes simplex virus)
- Fetal bleeding disorders (e.g. haemophilia)
- Prematurity (< 34 weeks).

Where there is clear evidence of acute fetal compromise (e.g. prolonged deceleration greater than three minutes), fetal blood sampling should not be undertaken and the baby should be delivered urgently.✓

Prolonged use of maternal facial oxygen therapy may be harmful to the fetus and should be avoided. There is no research evidence evaluating the benefits or risks associated with the short-term use of maternal facial oxygen therapy in cases of suspected fetal compromise.Ⓒ

During episodes of abnormal FHR patterns when the mother is lying supine, the mother should adopt the left-lateral position.Ⓑ

In cases of uterine hypercontractility in association with oxytocin infusion and with a suspicious or pathological CTG, the oxytocin infusion should be decreased or discontinued.Ⓑ

In the presence of abnormal FHR patterns and uterine hypercontractility not secondary to oxytocin infusion, tocolysis should be considered. A suggested regime is **subcutaneous terbutaline 0.25 milligrams.**Ⓐ

In cases of suspected or confirmed acute fetal compromise, delivery should be accomplished as soon as possible, accounting for the severity of the FHR abnormality and relevant maternal factors. The accepted standard has been that ideally this should be accomplished within 30 minutes.Ⓑ

Classification of fetal blood sample (FBS) results Ⓒ

Fetal blood sample result (pH)[a]	Subsequent action
≥ 7.25	FBS should be repeated if the FHR abnormality persists
7.21–7.24	Repeat FBS within 30 minutes or consider delivery if rapid fall since last sample
≤ 7.20	Delivery indicated

a: All scalp pH estimations should be interpreted taking into account the previous pH measurement, the rate of progress in labour and the clinical features of the mother and baby.

Education and training

Continuous EFM only provides a printed recording of the FHR pattern. The interpretation of the FHR record is subject to human error. Education and training improve standards of evaluating the FHR.

Trusts should ensure that staff with responsibility for performing and interpreting the results of EFM should receive annual training with assessment to assure that their skills are kept up-to-date. Details of key elements of training are in the full guideline.Ⓒ

Risk management and the use of EFM

EFM traces should be kept for a minimum of 25 years.Ⓒ

Tracer systems should be developed to ensure that CTGs removed for any purpose (e.g. risk management, teaching purposes) can always be located.Ⓒ

Key outcome measures

The key outcome measures that should be used to assess the impact and role of EFM are summarised below.

Absolute outcome measures of fetal/neonatal hypoxia to be collected at a local and regional level should be: B

- Perinatal death.
- Cerebral palsy.
- Neurodevelopmental disability.

Collection and interpretation at a national level would then be possible.

Intermediate fetal/neonatal measures of fetal hypoxia to be collected should be: B

- Umbilical artery acid-base status.
- Apgar score at five minutes.
- Neonatal encephalopathy.

These should be collected on a local (hospital/Trust) level.

Maternal outcome measures that should be collected include: C

- Operative delivery rates (caesarean section and instrumental vaginal delivery).

These should be collected on a local (hospital/Trust) level.

Umbilical artery acid-base status should be assessed by collection of paired samples from the umbilical artery and umbilical vein. B

Umbilical artery acid-base status should be performed as a minimum after: C

- emergency caesarean section is performed
- instrumental vaginal delivery is performed
- a fetal blood sample has been performed in labour
- birth, if the baby's condition is poor.

Induction of labour

Issue date – June 2001 **Review date** – January 2004

EVIDENCE LEVELS

The definitions of the types of evidence used in this guideline originate from the US Agency for Healthcare Policy and Research.

Levels of evidence

Level	Type of evidence
Ia	Evidence obtained from systematic review of meta-analysis of randomised controlled trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
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The grading scheme used was based on a scheme formulated by the Clinical Outcomes Group (COG) of the NHS Executive.

Grading of recommendations

Grade	Requirements
Ⓐ	Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)
Ⓑ	Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of the recommendation (evidence levels IIa, IIb, III)

Grading of recommendations (continued)

Grade	Requirements
C	Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

Good practice points

✓	Recommended good practice based on the clinical experience of the Guideline Development Group.

For the purposes of this guideline, induction of labour is defined as an intervention designed to artificially initiate uterine contractions leading to progressive dilatation and effacement of the cervix and birth of the baby. This includes both women with intact membranes and women with spontaneous rupture of the membranes but who are not in labour. As with any other intervention induction of labour may have unwanted side-effects. Induction of labour is indicated when it is agreed that the fetus or mother will benefit from a higher probability of a healthy outcome than if birth is delayed. The process of induction of labour should only be considered when vaginal delivery is felt to be the appropriate route of delivery.

Induction of labour is a common procedure, about 20% of pregnant women will have labour induced for a variety of reasons. Induction does not usually involve just a single intervention but is a complex set of interventions and as such presents challenges for both clinicians and mothers.

The guideline remit includes:

- Conditions which may affect the safety and efficacy of induction of labour e.g. previous caesarean section.
- Indications for induction of labour for healthy women with an uncomplicated pregnancy are considered, e.g. prolonged pregnancy, prelabour rupture of membranes at term. Variation in this policy for specific conditions are also included e.g. diabetes.

The risks and benefits of induction of labour as an intervention for specific clinical conditions arising in pregnancy are not included e.g. pre-eclampsia.

Care during induction of labour

Women centred care
Women must be able to make informed choices regarding their care or treatment via access to evidence based information. These choices should be recognised as an integral part of the decision making process.Ⓒ

Place of induction
For women who are healthy and have had an otherwise uncomplicated pregnancy, induction of labour with vaginal prostaglandin E_2 agents can be conducted on antenatal wards, prior to the active phase of labour.Ⓒ

When undertaking induction of labour of women with recognised risk factors (e.g. suspected fetal growth compromise, previous caesarean section or high parity) the induction process should not occur on an antenatal ward.Ⓒ

Fetal surveillance and induction of labour
Wherever induction of labour occurs, facilities should be available for continuous uterine and fetal heart rate monitoring.Ⓒ

Fetal wellbeing should be confirmed immediately prior to induction of labour.Ⓒ

Following induction of labour with vaginal prostaglandins (PGE_2) fetal well-being should be established once contractions are detected or reported.Ⓒ

For women who are healthy and have had an otherwise uncomplicated pregnancy the assessment of fetal well-being following the administration of vaginal prostaglandins should comprise of an initial assessment with continuous electronic fetal monitoring (EFM) and once normality is confirmed intermittent monitoring can be used.Ⓒ

Where oxytocin is being used for induction or augmentation of labour continuous electronic fetal monitoring should be used.Ⓒ

Uterine hypercontractility with induction agents.
For the purpose of this guideline uterine hypercontractility is defined as:

- without FHR changes included uterine tachysystole (>5 contractions per 10 minutes for at least 20 minutes) and uterine hypersystole/hypertonus (a contraction lasting at least two minutes).
- with FHR changes denote uterine hyperstimulation syndrome (tachysystole or hypersystole with fetal heart rate changes such as persistent decelerations, tachycardia or decreased short term variability).

Prolonged use of maternal facial oxygen therapy may be harmful to the fetus and should be avoided. There is no research evidence evaluating the benefits or risks associated with the short-term use of maternal facial oxygen therapy in cases of suspected fetal compromise.Ⓒ

In cases of uterine hypercontractility with a suspicious or pathological cardiotocograph (CTG), secondary to oxytocin infusions, the oxytocin infusion should be decreased or discontinued.Ⓑ A grading system for suspicious or pathological CTG is given below, incorporating both the proposed definitions of FHR patterns and categorisation schemes:

Categorisation of fetal heart rate traces

Category	Definition
Normal	A CTG where all four features fall into the reassuring category.
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Categorisation of fetal heart rate (FHR) features

Feature	Baseline (bpm)	Variability (bpm)	Decelerations	Accelerations
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Abnormal	<100 >180 Sinusoidal pattern ≥ 10 minutes	<5 for ≥ 90 minutes	Atypical variable decelerations Late decelerations Single prolonged deceleration >3 minutes	

In the presence of abnormal FHR patterns and uterine hypercontractility (not secondary to oxytocin infusion) tocolysis should be considered. A suggested regime is **subcutaneous terbutaline 0.25 milligrams.**Ⓐ

In cases of suspected or confirmed acute fetal compromise, delivery should be accomplished as soon as possible, taking account of the severity of the FHR abnormality and relevant maternal factors. The accepted standard has been that ideally this should be accomplished within 30 minutes.Ⓑ

Care of higher risk pregnancies
When undertaking induction of labour of women with recognised risk factors (e.g. suspected fetal growth compromise, previous caesarean section and high parity):Ⓒ

- The clinical discussion regarding the timing and method of induction of labour should be undertaken at consultant level.

- The induction process should not occur on an antenatal ward.

Indications for induction of labour

Prolonged pregnancy

- Population studies indicate that the risk of stillbirth increases from 1 per 3000 ongoing pregnancies at 37 weeks to 3 per 3000 ongoing pregnancies at 42 weeks to 6 per 3000 ongoing pregnancies at 43 weeks.
- A policy of offering routine induction of labour after 41 weeks reduces perinatal mortality without increasing the caesarean section rate.
- Data from a cohort study revealed that at 40 weeks only 58% of the population had delivered. This increased to 74% by 41 weeks and to 82% by 42 weeks. A policy of induction of labour prior to 41 weeks would generate an increase in workload without reducing perinatal mortality.

An ultrasound to confirm gestation should be offered before 20 weeks gestation as this reduces the need for induction for perceived post term pregnancy.Ⓐ

Women with uncomplicated pregnancies should be offered induction of labour beyond 41 weeks.Ⓐ

From 42 weeks women who decline induction of labour should be offered increased antenatal monitoring consisting of a twice weekly CTG and ultrasound estimation of maximum amniotic pool depth.Ⓐ

Diabetes in pregnancy

UK population studies show a four or five fold increase in perinatal mortality rate (including an increased rate of late fetal death) in pregnancies in women with diabetes in pregnancy compared to the general population.

Women who have pregnancies complicated by diabetes should be offered induction of labour prior to their estimated date for delivery.Ⓒ

Induction of labour in the presence of prelabour rupture of the membranes (PROM)

- Prelabour rupture of the membranes (PROM) occurs in 6–19% of term pregnancies.
- The risks of PROM at term relate to maternal/neonatal infection and prolapsed cord. Epidemiological data on time interval from PROM to spontaneous labour suggests that most (86%) women go into spontaneous labour within 24hrs of rupturing their membranes. The rate of spontaneous labour after this is about 5% per day.
- As the time between the rupture of the membranes and the onset of labour increases, so do the risks of maternal and fetal infection. Induction of labour reduces these risks.

Women with prelabour rupture of the membranes (PROM) at term (>37 weeks) should be offered a choice of immediate induction of labour **or** expectant management.Ⓐ

Expectant management of women with prelabour rupture of the membranes at term should not exceed 96 hours following membrane rupture.Ⓐ

Multifetal pregnancy, macrosomia and a history of precipitate labour were also considered by the guideline development group for inclusion within this section, but there was insufficient evidence upon which to base any recommendations.

Induction of labour for maternal request prior to 41 weeks

Where resources allow, maternal request for induction of labour should be considered when there are compelling psychological or social reasons and the woman has a favourable cervix.✓

Method of induction of labour in specific clinical situations

Membrane sweeping

Prior to formal induction of labour, women should be offered sweeping of the membranes.Ⓐ

When membrane sweeping is proposed discussions should include information which informs women that membrane sweeping:Ⓐ

- is not associated with an increase in maternal or neonatal infection.
- is associated with increased levels of discomfort during the procedure and bleeding.

Oxytocin compared to prostaglandins for induction of labour
Prostaglandins should be used in preference to using oxytocin when induction of labour is undertaken in either nulliparous or multiparous women with intact membranes regardless of their cervical favourability.Ⓐ

Either prostaglandins or oxytocin may be used when induction of labour is undertaken in nulliparous or multiparous women who have ruptured membranes, regardless of cervical status, as they are equally effective.Ⓐ

Comparison of intracervical and intravaginal prostaglandins (PGE_2)
When induction of labour is undertaken with prostaglandins intravaginal PGE_2 should be used in preference to intracervical preparations as they are equally effective and administration of vaginal PGE_2 is less invasive.Ⓐ

Comparison of different preparations of vaginal prostaglandin (PGE_2)
Given that they are clinically equivalent, when induction of labour is undertaken with vaginal PGE_2 preparations, vaginal tablets should be considered in preference to gel formulations.Ⓐ

Recommended regimens for vaginal PGE_2 preparations include:Ⓒ

- PGE_2 tablets:
  - 3 milligrams PGE_2 6–8 hourly
  - the maximum total dose is 6 milligrams for all women.
- PGE_2 gels:
  - 2 milligrams PGE_2 in nulliparous women with an unfavourable cervix. (Bishops score <4)
  - 1 milligram for all other women
  - in either, a second dose of 1–2 milligrams can be administered 6 hours later

  - the maximum dose is 4 milligrams PGE_2 for nulliparous women with an unfavourable cervix and 3 milligrams for all other women.

Comparison of different regimens of oxytocin administration
Oxytocin should not be started for 6 hours following administration of vaginal prostaglandins.Ⓒ

In women with intact membranes amniotomy should be performed where feasible prior to commencement of an infusion of oxytocin.Ⓒ

When induction of labour is undertaken with oxytocin the recommended regimen is:Ⓒ

- A starting dose of 1–2 milliunits per minute.
- Increased at intervals of 30 minutes or more.
- The minimum dose possible of oxytocin should be used and this should be titrated against uterine contractions aiming for a maximum of 3–4 contractions every 10 minutes.
- Adequate contractions may be established at 12 milliunits per minute.
- In the summary of product characteristics (SPC) the licensed maximum dose is 20 milliunits per minute.
- If higher doses are used the maximum dose used should not exceed 32 milliunits per minute.

Local protocols for delivery of oxytocin for induction of labour should:Ⓒ

- Specify and use the dose of oxytocin being delivered (milliunits per minute or mU/min) in preference to the volume of fluid being infused (millilitres per minute or ml/min).
- Be delivered through a syringe driver or via an infusion pump with a non-return valve.

To reduce error, a standard dilution should always be used. Suggested standardised dilutions and dose regimens include: Ⓒ

- 30IU oxytocin in 500ml of normal saline, hence 1ml/hr = 1 milliunit oxytocin per minute.
- 10IU oxytocin in 500ml of normal saline, hence 3mls/hr = 1 milliunit oxytocin per minute.

Suggested standardised dilutions and dose regimens Ⓒ

Time after starting (mins)	Oxytocin dose (mU/min)	Volume infused (mls/hour)	
		Dilution 30IU oxytocin in 500ml normal saline	Dilution 10IU oxytocin in 500ml normal saline
0	1	1	3
30	2	2	6
60	4	4	12
90	8	8	24
120	12	12	36
150	16	16	48
180	20	20	60
210	24	24	72
240	28	28	84
270	32	32	96

Doses highlighted in blue type are quantities above those referred to in the SPC of 20 milliunits per minute

INTERVENTIONAL PROCEDURE

Microwave endometrial ablation

new

Issue date – August 2003

Current evidence on the safety and efficacy of microwave endometrial ablation appears adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance.

It is recommended that the Medical Devices Agency (MDA) safety notices on endometrial ablation should be followed (MDA [1998] SN 9812 *Devices used for endometrial ablation achieved by thermal means*, and MDA [1999] SN 1999(18) *Devices used for endometrial ablation*, available from www.medical-devices.gov.uk).

Proper training in the performance of microwave endometrial ablation is required. The British Society for Gynaecological Endoscopy will be issuing training standards on the procedure.

TECHNOLOGY APPRAISAL

Routine antenatal anti-D prophylaxis for RhD negative women

Issue date – May 2002 **Review date** – March 2005

It is recommended that routine antenatal anti-D prophylaxis (RAADP) is offered to all non-sensitised pregnant women who are RhD negative.

The clinician (obstetrician, midwife or general practitioner) responsible for the prenatal care of a non-sensitised RhD-negative woman should discuss with her RAADP and the options available so that the woman can make an informed choice about treatment. This discussion should include the circumstances where RAADP would be neither necessary nor cost effective. Such circumstances might include those where the woman:

- has opted to be sterilised after the birth of the baby
- is in a stable relationship with the father of the child, and the father is known or found to be RhD negative
- is certain that she will not have another child after her current pregnancy.

The difference between RAADP (i.e. routine prophylaxis at 28 and 34 weeks) and prophylactic anti-D given because of likely sensitisation (see below) should be clearly explained to the woman.

A woman's use of RAADP at 28 and 34 weeks should not be affected by whether she has already had antenatal anti-D prophylaxis (AADP) for a potentially sensitising event early in pregnancy. A woman's use of postpartum anti-D prophylaxis should similarly not be affected by whether she has had RAADP or AADP as the result of a sensitising event. Beyond this, AADP for a potentially sensitising event and postpartum anti-D prophylaxis are not the remit of this guidance. These matters are covered by the Royal College of Obstetricians and Gynaecologists' 'Green Top' 1999 guideline: *Use of Anti-D Immunoglobulin for Rh Prophylaxis*.

It is recommended that high-quality information, validated and produced at the national level, is made available to RhD-negative women and the relevant healthcare professionals.

Tension-free vaginal tape (Gynecare TVT) for stress incontinence

Issue date – February 2003 **Review date** – February 2006

The tension-free vaginal tape (TVT) procedure is recommended as one of a range of surgical options for women with uncomplicated urodynamic stress incontinence in whom conservative management has failed.

In making the decision to use TVT, the patient should be fully informed of the advantages and drawbacks of the relevant surgical procedures. The considerations should include:

- the advantages of a minimal-access technique, set against the disadvantage of the absence of data on long-term effectiveness
- whether the woman is likely to have children subsequently
- whether the procedure will be used in conjunction with another procedure, such as vaginal hysterectomy or repair of prolapse.

The TVT procedure should be performed only by surgeons who have received appropriate training in the technique, and who regularly carry out surgery for stress incontinence in women.

Uterine artery embolisation for fibroids

Issue date – July 2003

There is uncertainty about the safety and efficacy of uterine artery embolisation (UAE). All clinicians wishing to undertake UAE should therefore:

- inform the clinical governance leads in their Trusts
- ensure that patients offered the procedure understand the uncertainty about its safety and efficacy, and provide them

with clear written information – use of the information for the public produced by NICE is recommended

- ensure that appropriate arrangements are in place for clinical audit or research
- involve a gynaecologist and an interventional radiologist in a team approach to patient selection and management
- submit data to the British Society of Interventional Radiology registry.

Infections and infectious diseases

Clinical Guideline

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Infection control – Prevention of healthcare-associated infection in primary and community care

Issue date – June 2003 **Review date** – June 2007

Table 1 Levels of evidence

Level	Type of evidence
Ia	evidence from meta-analysis of randomised controlled trials
Ib	evidence from at least one randomised controlled trial
IIa	evidence from at least one controlled study without randomisation
IIb	evidence from at least one other type of quasi-experimental study
III	evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case–control studies
IV	evidence from expert committee reports or opinions and/or clinical experience of respected authorities

Adapted from Eccles M, Mason J (2001) How to develop cost-conscious guidelines. *Health Technology Assessment* 5(16): 8

Table 2 Grading of recommendations

Grade	Evidence
Ⓐ	directly based on category I evidence
Ⓑ	directly based on category II evidence, or extrapolated recommendation from category I evidence
Ⓒ	directly based on category III evidence, or extrapolated recommendation from category I or II evidence
Ⓓ	directly based on category IV evidence, or extrapolated recommendation from category I, II or III evidence
Health and Safety legislation (H&S)	directly based on UK health and safety legislation

This guideline makes recommendations on the standard principles for preventing healthcare-associated infections and on measures for preventing infections associated with three specific aspects of care: the use of long-term urinary catheters, enteral feeding systems, and central venous catheters. Each of these includes education of patients, carers and healthcare personnel.

Standard principles

The recommendations on standard principles provide guidance on infection control precautions that should be applied by all healthcare personnel, and other carers, to the care of patients in community and primary care settings.

The recommendations are divided into three broad recommendation headings:

- hand hygiene
- the use of personal protective equipment
- the safe use and disposal of sharps.

GENERAL RECOMMENDATIONS

- Everyone involved in providing care in the community should be educated about standard principles and trained in hand decontamination, the use of protective clothing and the safe disposal of sharps. Ⓓ
- Adequate supplies of liquid soap, handrub, towels and sharps containers should be made available wherever care is delivered. Ⓓ

HAND HYGIENE

- Hands must be decontaminated immediately before each and every episode of direct patient contact or care and after any activity or contact that could potentially result in hands becoming contaminated. Ⓑ
- Hands that are visibly soiled, or potentially grossly contaminated with dirt or organic material, must be washed with liquid soap and water Ⓐ
- Hands must be decontaminated, preferably with an alcohol based handrub unless hands are visibly soiled, between

caring for different patients and between different care activities for the same patient.Ⓐ

- Before regular hand decontamination begins, all wrist and ideally hand jewellery should be removed. Cuts and abrasions must be covered with waterproof dressings. Fingernails should be kept short, clean and free from nail polish.Ⓓ
- An effective handwashing technique involves three stages: preparation, washing and rinsing, and drying. Preparation requires wetting hands under tepid running water **before** applying liquid soap or an antimicrobial preparation. The handwash solution must come into contact with **all** of the surfaces of the hand. The hands must be **rubbed** together vigorously for a minimum of 10–15 seconds, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers. Hands should be rinsed thoroughly before drying with good quality paper towels.Ⓓ
- When decontaminating hands using an alcohol handrub, hands should be free from dirt and organic material. The handrub solution must come into contact with all surfaces of the hand. The hands must be **rubbed** together vigorously, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers, until the solution has evaporated and the hands are dry.Ⓓ
- An emollient hand cream should be applied regularly to protect skin from the drying effects of regular hand decontamination. If a particular soap, antimicrobial hand wash or alcohol product causes skin irritation an occupational health team should be consulted.Ⓓ

USE OF PERSONAL PROTECTIVE EQUIPMENT

- Selection of protective equipment should be based on an assessment of the risk of transmission of microorganisms to the patient, and the risk of contamination of the healthcare practitioner's clothing and skin by patients' blood, body fluids, secretions or excretions.Ⓓ H&S
- Gloves must be worn for invasive procedures, contact with sterile sites and non-intact skin or mucous membranes, and all activities that have been assessed as carrying a risk of

exposure to blood, body fluids, secretions or excretions, or to sharp or contaminated instruments. Ⓓ H&S

- Gloves must be worn as single-use items. They must be put on immediately before an episode of patient contact or treatment and removed as soon as the activity is completed. Gloves must be changed between caring for different patients, and between different care or treatment activities for the same patient. Ⓓ H&S
- Gloves must be disposed of as clinical waste and hands decontaminated after the gloves have been removed. Ⓓ H&S
- Gloves that are acceptable to healthcare personnel and that conform to European Community (CE) standards must be available. H&S
- Sensitivity to natural rubber latex in patients, carers and healthcare personnel must be documented, and alternatives to natural rubber latex gloves must be available. H&S
- Neither powdered gloves nor polythene gloves should be used in healthcare activities. Ⓓ H&S
- Disposable plastic aprons should be worn when there is a risk that clothing may be exposed to blood, body fluids, secretions or excretions, with the exception of sweat. Ⓓ H&S
- Full-body fluid-repellent gowns must be worn where there is a risk of extensive splashing of blood, body fluids, secretions or excretions, with the exception of sweat, onto the skin or clothing of healthcare practitioners (for example when assisting with childbirth). Ⓓ H&S
- Plastic aprons should be worn as single-use items, for one procedure or episode of patient care, and then discarded and disposed of as clinical waste. Ⓓ H&S
- Face masks and eye protection must be worn where there is a risk of blood, body fluids, secretions or excretions splashing into the face and eyes. Ⓓ H&S
- Respiratory protective equipment, for example a particulate filter mask, must be used when clinically indicated. Ⓓ H&S

SAFE USE AND DISPOSAL OF SHARPS

- Sharps must not be passed directly from hand to hand, and handling should be kept to a minimum. Ⓓ H&S

- Needles must not be recapped, bent, broken or disassembled before use or disposal.Ⓓ H&S
- Used sharps must be discarded into a sharps container (conforming to UN3291 and BS 7320 standards) at the point of use by the user. These must not be filled above the mark that indicates that they are full.Ⓓ H&S
- Containers in public areas must be located in a safe position, and must not be placed on the floor. They must be disposed of by the licensed route in accordance with local policy.Ⓓ H&S
- Needle safety devices must be used where there are clear indications that they will provide safer systems of working for healthcare personnel.Ⓓ H&S

Care of patients with long-term urinary catheters

These guidelines apply to adults and children and should be used in conjunction with the guidance on standard principles (Section 1.1). These guidelines focus on preventing infection. However, because infection has a complex interrelationship with encrustation and blockage, these aspects of catheter management are also addressed. The recommendations are divided into five distinct interventions:

- education of patients, their carers and healthcare personnel
- assessing the need for catheterisation
- selection of catheter drainage options
- catheter insertion
- catheter maintenance.

EDUCATION OF PATIENTS, THEIR CARERS AND HEALTHCARE PERSONNEL

- Patients and carers should be educated about and trained in techniques of hand decontamination, insertion of intermittent catheters where applicable, and catheter management before discharge from hospital.Ⓓ
- Community and primary healthcare personnel must be trained in catheter insertion, including suprapubic catheter replacement and catheter maintenance.Ⓓ
- Follow-up training and ongoing support of patients and

carers should be available for the duration of long-term catheterisation.Ⓓ

ASSESSING THE NEED FOR CATHETERISATION

- Indwelling urinary catheters should be used only after alternative methods of management have been considered.Ⓓ
- The patient's clinical need for catheterisation should be reviewed regularly and the urinary catheter removed as soon as possible.Ⓓ
- Catheter insertion, changes and care should be documented.Ⓓ

CATHETER DRAINAGE OPTIONS

- Following assessment, the best approach to catheterization that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected.Ⓒ
- Intermittent catheterisation should be used in preference to an indwelling catheter if it is clinically appropriate and a practical option for the patient.Ⓐ
- For urethral and suprapubic catheters, the choice of catheter material and gauge will depend on an assessment of the patient's individual characteristics and predisposition to blockage.Ⓓ
- In general, the catheter balloon should be inflated with 10 ml of sterile water in adults and 3–5 ml in children.Ⓓ
- In patients for whom it is appropriate, a catheter valve may be used as an alternative to a drainage bag.Ⓐ

CATHETER INSERTION

- All catheterisations carried out by healthcare personnel should be aseptic procedures. After training, healthcare personnel should be assessed for their competence to carry out these types of procedures.Ⓓ
- Intermittent self-catheterisation is a clean procedure. A lubricant for single-patient use is required for nonlubricated catheters.Ⓐ

- For urethral catheterisation, the meatus should be cleaned before insertion of the catheter, in accordance with local guidelines/policy.Ⓓ
- An appropriate lubricant from a single-use container should be used during catheter insertion to minimise urethral trauma and infection.Ⓓ

CATHETER MAINTENANCE

- Indwelling catheters should be connected to a sterile closed urinary drainage system or catheter valve.Ⓓ
- Healthcare personnel should ensure that the connection between the catheter and the urinary drainage system is not broken except for good clinical reasons, (for example changing the bag in line with the manufacturer's recommendations).Ⓓ
- Healthcare personnel must decontaminate their hands and wear a new pair of clean, non-sterile gloves before manipulating a patient's catheter, and must decontaminate their hands after removing gloves.Ⓓ
- Carers and patients managing their own catheters must wash their hands before and after manipulation of the catheter, in accordance with the recommendations in the standard principles section (above).Ⓐ
- Urine samples must be obtained from a sampling port using an aseptic technique.Ⓓ
- Urinary drainage bags should be positioned below the level of the bladder, and should not be in contact with the floor.Ⓓ
- A link system should be used to facilitate overnight drainage, to keep the original system intact.Ⓓ
- The urinary drainage bag should be emptied frequently enough to maintain urine flow and prevent reflux, and should be changed when clinically indicated.Ⓓ
- The meatus should be washed daily with soap and water.Ⓐ
- Each patient should have an individual care regimen designed to minimise the problems of blockage and encrustation. The tendency for catheter blockage should be documented in each newly catheterised patient.Ⓓ

- Bladder instillations or washouts must not be used to prevent catheter-associated infection.Ⓐ
- Catheters should be changed only when clinically necessary, or according to the manufacturer's current recommendations.Ⓓ
- Antibiotic prophylaxis when changing catheters should only be used for patients with a history of catheter-associated urinary tract infection following catheter change, or for patients who have a heart valve lesion, septal defect, patent ductus or prosthetic valve.Ⓑ
- Reusable intermittent catheters should be cleaned with water and stored dry in accordance with the manufacturer's instructions.Ⓓ

Care during enteral feeding

These guidelines apply to adults and children and should be used in conjunction with the guidance on standard principles above The recommendations are divided into four distinct interventions:

- education of patients, their carers and healthcare personnel
- preparation and storage of feeds
- administration of feeds
- care of insertion site and enteral feeding tube.

EDUCATION OF PATIENTS, THEIR CARERS AND HEALTHCARE PERSONNEL

- Patients and carers should be educated about and trained in the techniques of hand decontamination, enteral feeding and the management of the administration system before being discharged from hospital.Ⓓ
- Community staff should be trained in enteral feeding and management of the administration system.Ⓓ
- Follow-up training and ongoing support of patients and carers should be available for the duration of home enteral tube feeding.Ⓓ

PREPARATION AND STORAGE OF FEEDS

- Wherever possible pre-packaged, ready-to-use feeds should be used in preference to feeds requiring decanting, reconstitution or dilution.Ⓐ
- The system selected should require minimal handling to assemble, and be compatible with the patient's enteral feeding tube.Ⓑ
- Effective hand decontamination must be carried out before starting feed preparation.Ⓐ
- When decanting, reconstituting or diluting feeds, a clean working area should be prepared and equipment dedicated for enteral feed use only should be used.Ⓓ
- Feeds should be mixed using cooled boiled water or freshly opened sterile water and a no-touch technique.Ⓓ
- Feeds should be stored according to the manufacturer's instructions and, where applicable, food hygiene legislation.Ⓓ
- Where ready-to-use feeds are not available, feeds may be prepared in advance, stored in a refrigerator, and used within 24 hours.Ⓓ

ADMINISTRATION OF FEEDS

- Minimal handling and an aseptic no-touch technique should be used to connect the administration system to the enteral feeding tube.Ⓒ
- Ready-to-use feeds may be given for a whole administration session, up to a maximum of 24 hours. Reconstituted feeds should be administered over a maximum 4-hour period.Ⓒ
- Administration sets and feed containers are for single use and must be discarded after each feeding session.Ⓑ

CARE OF INSERTION SITE AND ENTERAL FEEDING TUBE

- The stoma should be washed daily with water and dried thoroughly.Ⓓ
- To prevent blockage, the enteral feeding tube should be flushed with fresh tap water before and after feeding or administering medications. Enteral feeding tubes for patients who are immunosuppressed should be flushed with

either cooled freshly boiled water or sterile water from a freshly opened container.Ⓓ

Care of patients with central venous catheters

These recommendations apply to the care in the community of all adults and children with central venous catheters that are being used for the administration of fluids, medications, blood components and/or total parenteral nutrition. They should be used in conjunction with the recommendations on standard principles above.

These recommendations do not specifically address the more technical aspects of the care of patients receiving haemodialysis, who will generally have their central venous catheters managed in dialysis centres.

The recommendations are divided into four intervention categories:

- education of patients, their carers and healthcare personnel
- general asepsis
- catheter site care
- standard principles for catheter management.

EDUCATION OF PATIENTS, THEIR CARERS AND HEALTHCARE PERSONNEL

- Before discharge from hospital, patients and their carers should be taught any techniques they may need to use to prevent infection and safely manage a central venous catheter.Ⓓ
- Community healthcare personnel caring for a patient with a central venous catheter should be trained, and assessed as competent, in using and consistently adhering to the infection prevention practices described in this guideline.Ⓓ
- Follow-up training and support should be available to patients with central venous catheters and their carers.Ⓓ

GENERAL ASEPSIS

- An aseptic technique must be used for catheter site care and for accessing the system.Ⓑ
- Before accessing or dressing central venous catheters, hands

must be decontaminated either by washing with an antimicrobial liquid soap and water, or by using an alcohol handrub. Ⓐ

- Hands that are visibly soiled or contaminated with dirt or organic material must be washed with soap and water before using an alcohol handrub. Ⓐ
- Following hand antisepsis, clean gloves and a no-touch technique or sterile gloves should be used when changing the insertion site dressing. Ⓓ

CATHETER SITE CARE

- Preferably, a sterile, transparent, semipermeable polyurethane dressing should be used to cover the catheter site. Ⓐ
- If a patient has profuse perspiration, or if the insertion site is bleeding or oozing, a sterile gauze dressing is preferable to a transparent, semi-permeable dressing. Ⓓ
- Gauze dressings should be changed when they become damp, loosened or soiled, and the need for a gauze dressing should be assessed daily. A gauze dressing should be replaced by a transparent dressing as soon as possible. Ⓓ
- Transparent dressings should be changed every 7 days, or sooner if they are no longer intact or moisture collects under the dressing. Ⓐ
- Dressings used on tunnelled or implanted central venous catheter sites should be replaced every 7 days until the insertion site has healed, unless there is an indication to change them sooner. Ⓐ
- An alcoholic chlorhexidine gluconate solution should be used to clean the catheter site during dressing changes, and allowed to air dry. An aqueous solution of chlorhexidine gluconate should be used if the manufacturer's recommendations prohibit the use of alcohol with the product. Ⓐ
- Individual sachets of antiseptic solution or individual packages of antiseptic-impregnated swabs or wipes should be used to disinfect the dressing site. Ⓓ
- Healthcare personnel should ensure that catheter-site care is

compatible with catheter materials (tubing, hubs, injection ports, luer connectors and extensions) and carefully check compatibility with the manufacturer's recommendations.Ⓓ

GENERAL PRINCIPLES FOR CATHETER MANAGEMENT

- The injection port or catheter hub should be decontaminated using either alcohol or an alcoholic solution of chlorhexidine gluconate before and after it has been used to access the system.Ⓒ
- In-line filters should not be used routinely for infection prevention.Ⓓ
- Antibiotic lock solutions should not be used routinely to prevent catheter-related bloodstream infections (CRBSI).Ⓐ
- Systemic antimicrobial prophylaxis should not be used routinely to prevent catheter colonisation or CRBSI, either before insertion or during the use of a central venous catheter.Ⓐ
- Preferably, a single lumen catheter should be used to administer parenteral nutrition. If a multilumen catheter is used, one port must be exclusively dedicated for total parenteral nutrition, and all lumens must be handled with the same meticulous attention to aseptic technique.Ⓓ
- Preferably, a sterile 0.9 percent sodium chloride injection should be used to flush and lock catheter lumens.Ⓓ
- When recommended by the manufacturer, implanted ports or opened-ended catheter lumens should be flushed and locked with heparin sodium flush solutions.Ⓓ
- Systemic anticoagulants should not be used routinely to prevent CRBSI.Ⓓ
- If needleless devices are used, the manufacturer's recommendations for changing the needleless components should be followed.Ⓓ
- When needleless devices are used, healthcare personnel should ensure that all components of the system are compatible and secured, to minimise leaks and breaks in the system.Ⓓ
- When needleless devices are used, the risk of contamination should be minimised by decontaminating the access port

with either alcohol or an alcoholic solution of chlorhexidine gluconate before and after using it to access the system.Ⓓ

- In general, administration sets in continuous use need not be replaced more frequently than at 72-hour intervals unless they become disconnected or a catheter-related infection is suspected or documented.Ⓐ
- Administration sets for blood and blood components should be changed every 12 hours, or according to the manufacturer's recommendations.Ⓓ
- Administration sets used for total parenteral nutrition infusions should generally be changed every 24 hours. If the solution contains only glucose and amino acids, administration sets in continuous use do not need to be replaced more frequently than every 72 hours.Ⓓ

TECHNOLOGY APPRAISAL

Interferon alpha and ribavirin for hepatitis C

Issue date – October 2000 **Review date** – October 2003

Interferon alpha and ribavirin as combination therapy is recommended for the treatment of moderate to severe hepatitis C (defined as histological evidence of significant scarring (fibrosis) and/or significant necrotic inflammation), at standard doses for patients over the age of 18 years as follows:

- All treatment-naïve patients (that is, those who have not previously had interferon alpha monotherapy or combination therapy) and all patients who have been treated with interferon alpha monotherapy, and have had some response but have since relapsed. Such treatment should be continued for 6 months for all patients.
- A further 6 months combination therapy is recommended only for patients infected with hepatitis C virus of genotype 1, who respond to therapy by becoming clear of circulating viral RNA as detected by polymerase chain reaction (PCR) in the first 6 months.
- Those in whom liver biopsy poses a substantially increased risk (such as patients with haemophilia) may be treated on clinical grounds without histology.

Therapy involving either or both of these drugs is not in general recommended for patients who are continuing intravenous drug users. Only where the prescribing clinician can be reliably assured that re-infection, compliance and drug interactions pose no problems should patients in this group be considered for combination therapy. Former intravenous drug users including those on oral maintenance therapy need not be excluded from therapy.

Therapy involving either or both of these drugs is not in general recommended for patients who are heavy users of alcohol, because of an increased risk of exacerbation of liver damage.

There is insufficient evidence for making recommendations on combination therapy for patients less than 18 years of age. There is also insufficient evidence for making recommendations for using combination therapy after liver transplantation.

Interferon alpha monotherapy should be considered only when ribavirin is contraindicated or not tolerated. The recently licensed pegylated interferon monotherapy has not been considered in this guidance.

These recommendations are consistent with the European Association of the Study of the Liver (EASL) guidelines with the exception that (see first bullet point above), those who relapse after initially successful treatment by monotherapy are recommended for 6 months of combination therapy without the necessity of a viral load test after 3 months.

TECHNOLOGY APPRAISAL

Oseltamivir and amantadine for the prophylaxis of influenza

Issue date – September 2003 **Review date** – August 2006

This guidance has been prepared in the expectation that vaccination against influenza is undertaken in accordance with national guidelines. Vaccination is the most effective way of preventing illness from influenza, and the drugs described in this guidance are not a substitute for vaccination. This guidance does not cover the circumstances of a pandemic, impending pandemic, or a widespread epidemic of a new strain of influenza to which there is little or no community resistance.

This guidance pertains only to circumstances where it is known that either influenza A or influenza B is circulating in the community (see below).

Oseltamivir is recommended for the post-exposure prophylaxis of influenza in at-risk people aged 13 years or older who are not effectively protected by vaccination and who have been exposed to someone with influenza-like illness (ILI) and are able to begin prophylaxis within 48 hours of exposure. People who are not effectively protected by vaccination include those who have not been vaccinated since the previous influenza season, or for whom:

- vaccination is contraindicated, or has yet to take effect
- vaccination has been carried out but the vaccine is not well matched to the strain of influenza virus circulating. (The Department of Health and the Welsh Assembly Government, acting on information from the Health Protection Agency, issue advice nationally each year on whether the vaccine and the circulating influenza virus are well matched.)

Exposure to ILI is defined as being in close contact with someone who lives in the same home environment as a person who has been suffering from symptoms of ILI.

At-risk people are defined, for the purpose of this guidance, as those who are in at least one of the following groups.

People who:

- have chronic respiratory disease (including asthma and chronic obstructive pulmonary disease)
- have significant cardiovascular disease (excluding people with hypertension only)
- have chronic renal disease
- are immunocompromised
- have diabetes mellitus
- are aged 65 years or older.

Oseltamivir is recommended for the post-exposure prophylaxis of influenza in at-risk people, aged 13 years and older and who can begin prophylaxis within 48 hours, whether or not they have been vaccinated, if they live in a residential care establishment where a resident or staff member has ILI. For the purposes of this guidance, a residential care establishment is defined as a place where the at-risk person resides in the long term in order to be provided with continuing care alongside a number of other individuals.

Oseltamivir is not recommended for post-exposure prophylaxis in healthy people up to age 65 years.

Oseltamivir is not recommended for the seasonal prophylaxis of influenza.

Amantadine is not recommended for either post-exposure or seasonal prophylaxis of influenza.

Community-based virological surveillance schemes should be used to determine when influenza virus is circulating in the community. Such schemes, including those organised by the Royal College of General Practitioners and the Health Protection Agency, should ensure that the onset of the circulation of influenza virus (A or B) within a defined area is identified as rapidly as possible. In Appendix D, definitions and numerical values of threshold levels for different categories of influenza activity are given.

TECHNOLOGY APPRAISAL

Zanamivir, oseltamivir and amantadine for the treatment of influenza

Issue date – February 2003 **Review date** – September 2005

This guidance has been prepared in the expectation that vaccination against influenza is undertaken in accordance with national guidelines. Vaccination is the most effective way of preventing illness from influenza, and the drugs described in this guidance are not a substitute for vaccination. This guidance does not cover the circumstances of a pandemic, impending pandemic or a widespread epidemic of a new strain of influenza to which there is little or no community resistance.

This guidance pertains only to circumstances where it is known that either influenza A or influenza B is circulating in the community (see below).

Zanamivir and oseltamivir are not recommended for the treatment of influenza in children or adults unless they are considered to be 'at risk'.

At-risk adults and children are defined for the purpose of this guidance as those who are in at least one of the following groups. People who:

- have chronic respiratory disease (including asthma and chronic obstructive pulmonary disease)
- have significant cardiovascular disease (excluding people with hypertension only)
- have chronic renal disease
- are immunocompromised
- have diabetes mellitus
- are aged 65 years or older.

Amantadine is not recommended for the treatment of influenza.

Within their licensed indications, zanamivir and oseltamivir are recommended for the treatment of at-risk adults who present with influenza-like illness (ILI) and who can start therapy within 48 hours of the onset of symptoms.

Within its licensed indications, oseltamivir is recommended for the treatment of at-risk children who present with ILI and who can start therapy within 48 hours of the onset of symptoms.

Community-based virological surveillance schemes should be used to indicate when influenza virus is circulating in the community. Community-based virological surveillance schemes, such as those organised by the Royal College of General Practitioners and the Public Health Laboratory Service, should be used to indicate when influenza virus is circulating in the community. Such schemes should ensure that the onset of the circulation of influenza virus (A or B) within a defined area is identified as rapidly as possible.

Injuries and accidents

Clinical Guideline

Triage, assessment, investigation and early management of head injury in infants, children and adults 193 NEW

CLINICAL GUIDELINE

Triage, assessment, investigation and early management of head injury in infants, children and adults

Issue date – June 2003 **Review date** – June 2005

EVIDENCE LEVELS

Following agreement with the Institute, the Guideline Development Group used classifications adapted from the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001), to summarise the evidence levels for reviewed studies.

Table 1a Levels of evidence used for studies on the development of clinical decision rules

Level	Type of evidence
1	Cohort study with consecutive patients and good reference standards, used to validate clinical decision rules
2	Cohort study with consecutive patients and good reference standards used to derive clinical decision rules (or validated on split samples only)
3	Non-consecutive study or without consistently applied reference standards
4	Case-control study, poor or non-independent reference standard
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or 'first principles'

Table 1b Levels of evidence used for systematic reviews

Level	Type of evidence
1	Systematic review (with homogeneity) of mostly level 1 studies
2	Systematic review (with homogeneity) of mostly level 2 studies
3	Systematic review (with homogeneity) of mostly level 3 studies

DERIVATION AND GRADING OF RECOMMENDATIONS

It was also agreed to adopt the Oxford Centre for Evidence-based Medicine classification for grade of recommendations (May 2001). This was used so that a symmetry with the levels of evidence classification could be achieved.

Table 2 Grading of recommendations

Grade	Evidence
Ⓐ	Consistent level 1 studies
Ⓑ	Consistent level 2 or 3 studies or extrapolations from level 1 studies
Ⓒ	Level 4 studies or extrapolations from level 2 or 3 studies
Ⓓ	Level 5 evidence or troublingly inconsistent or inconclusive studies of any level

This guideline addresses the triage, assessment, investigation and early management of head injury.

To support the use of this guideline, observation proformas, a sample referral letter, and suggested discharge advice are available from the NICE website (www.nice.org.uk). These can be downloaded and adapted for use as necessary.

DEFINITIONS

For the purposes of this guideline, it was agreed that infants are aged under 1 year, children are 1–15 years old and adults are aged 16 years or older. In certain circumstances, the age group 'infants and young children' (that is, those aged under 5 years) is used. Cut-off points of 10 years and 12 years are also used.

'Head injury' for the purposes of the guideline is defined as any trauma to the head, other than superficial injuries to the face. The primary patient outcome of concern throughout the guideline is 'clinically important brain injury'.

GENERAL

Glasgow Coma Scale

The assessment and classification of patients who have sustained a head injury should be guided primarily by the adult and paediatric versions of the Glasgow Coma Scale and its derivative the Glasgow Coma Score. Recommended versions are shown in Table 3, below. Good practice in the use of the Glasgow Coma Scale and Score should be adhered to at all times, following the principles below.

- Monitoring and exchange of information about individual patients should be based on the three separate responses on the GCS (for example, a patient scoring 13 based on scores of 4 on eye-opening, 4 on verbal response and 5 on motor response should be communicated as E4, V4, M5).Ⓓ
- If a total score is recorded or communicated, it should be based on a sum of 15, and to avoid confusion this denominator should be specified (for example, 13/15).Ⓓ
- The individual components of the GCS should be described in all communications and every note and should always accompany the total score.Ⓓ
- The paediatric version of the GCS should include a 'grimace' alternative to the verbal score to facilitate scoring in preverbal or intubated patients.Ⓓ
- Best practice in paediatric coma observation and recording as detailed by the National Paediatric Neuroscience Benchmarking Group should be followed at all times (these principles are detailed in Table 3).Ⓓ

Table 3 Glasgow Coma Scales

Adults

The Glasgow Coma Scale is scored between 3 and 15, 3 being the worst, and 15 the best. It is composed of three parameters: Best Eye Response, Best Verbal Response, Best Motor Response. The definition of these parameters is given below.

Best Eye Response (4)
1. No eye opening
2. Eye opening to pain
3. Eye opening to verbal command
4. Eyes open spontaneously

Best Verbal Response (5)
1. No verbal response

2. Incomprehensible sounds
3. Inappropriate words
4. Confused
5. Orientated

Best Motor Response (6)

1. No motor response
2. Extension to pain
3. Flexion to pain
4. Withdrawal from pain
5. Localising pain
6. Obeys commands

Children

The paediatric version of the Glasgow Coma Scale is scored between 3 and 15, 3 being the worst, and 15 the best. It is composed of three parameters: Best Eye Response, Best Verbal Response, Best Motor Response. The definition of these parameters is given below.

Best Eye Response (4)

1. No eye opening
2. Eye opening to pain
3. Eye opening to verbal command
4. Eyes open spontaneously

Best Verbal Response (5)

1. No vocal response
2. Occasionally whimpers and/or moans
3. Cries inappropriately
4. Less than usual ability and/or spontaneous irritable cry
5. Alert, babbles, coos, words or sentences to usual ability

Communication with the infant or child's caregivers is required to establish the best usual verbal response. A 'grimace' alternative to verbal responses should be used in pre-verbal or intubated patients.

Best Grimace Response (5)

1. No response to pain
2. Mild grimace to pain
3. Vigorous grimace to pain
4. Less than usual spontaneous ability or only response to touch stimuli
5. Spontaneous normal facial/oro-motor activity

Best Motor Response (6)

1. No motor response to pain
2. Abnormal extension to pain (decerebrate)

3. Abnormal flexion to pain (decorticate)
4. Withdrawal to painful stimuli
5. Localises to painful stimuli or withdraws to touch
6. Obeys commands or performs normal spontaneousmovements

Public health literature

- Public health literature and other non-medical sources of advice (for example, St John Ambulance, police officers) should encourage people who have any concerns following a head injury to themselves or to another person, regardless of the injury severity, to seek immediate medical advice.Ⓓ

Training in risk assessment

- It is recommended that GPs, nurse practitioners, dentists and paramedics should all be capable of assessing the presence or absence of the risk factors listed in 'Community health services and NHS minor injury clinics' below. Training should be available as required to ensure head injury triage accuracy in paramedics, GPs, nurse practitioners and dentists.Ⓓ

Support for families and carers

- There should be a protocol for all staff to introduce themselves to family members or carers and briefly explain what they are doing. In addition a photographic board with the names and titles of personnel in the hospital departments caring for patients with head injury can be helpful.Ⓓ
- Information sheets detailing the nature of head injury and any investigations likely to be used should be available in the A&E Department. The patient version of these NICE guidelines may be helpful.Ⓓ
- Staff should consider how best to share information with children and introduce them to the possibility of long-term complex changes in their parent or sibling. Literature produced by patient support groups may be helpful.Ⓓ
- Carers and relatives should be encouraged to talk and make physical contact (for example, holding hands) with the patient, although it is important for relatives and friends not

to feel that they have to spend many hours at the bedside. It is important that they also have a break and sleep from time to time. This may be an opportune moment to mention patient support organisations and introduce their literature.Ⓓ

- There should be a board/area displaying leaflets or contact details for patient support organisations either locally or nationally to enable family members to gather further information.Ⓓ

PRESENTATION AND REFERRAL

A person with a head injury may present via a telephone advice service or to a community health service or minor injury clinic. The following recommendations apply in these settings.

Telephone advice services

- Telephone advice services (for example, NHS Direct, A&E helplines) should refer people who have sustained a head injury to the emergency ambulance services (that is, 999) for emergency transport to A&E if they have experienced any of the following (alternative terms to facilitate communication are in parentheses).Ⓓ
  - Unconsciousness, or lack of full consciousness (for example, problems keeping eyes open).
  - Any focal (that is, restricted to a particular part of the body or a particular activity) neurological deficit since the injury (examples include problems understanding, speaking, reading or writing; loss of feeling in part of the body; problems balancing; general weakness; any changes in eyesight; and problems walking).
  - Any suspicion of a skull fracture or penetrating head injury (for example, clear fluid running from the ears or nose, black eye with no associated damage around the eye, bleeding from one or both ears, new deafness in one or both ears, bruising behind one or both ears, penetrating injury signs, visible trauma to the scalp or skull).
  - Any seizure ('convulsion' or 'fit') since the injury.
  - A high-energy head injury (for example, pedestrian struck

by motor vehicle, occupant ejected from motor vehicle, a fall from a height of greater than 1 metre or more than five stairs, diving accident, high-speed motor vehicle collision, rollover motor accident, accident involving motorised recreational vehicles, bicycle collision, or any other potentially high-energy mechanism). A lower threshold for height of falls should be used when dealing with infants and young children (that is, aged under 5 years).

  - The injured person or their carer is incapable of transporting the injured person safely to the hospital A&E department without the use of ambulance services (providing any other risk factors indicating A&E referral are present).

- Telephone advice services (for example, NHS Direct, A&E helplines) should refer people who have sustained a head injury to a hospital A&E department if the history related indicates the presence of any of the following risk factors (alternative terms to facilitate communication are in parentheses).Ⓓ
  - Any previous loss of consciousness ('knocked out') as a result of the injury, from which the injured person has now recovered.
  - Amnesia for events before or after the injury ('problems with memory'). The assessment of amnesia will not be possible in pre-verbal children and is unlikely to be possible in any child aged under 5 years.
  - Persistent headache since the injury.
  - Any vomiting episodes since the injury.
  - Any previous cranial neurosurgical interventions ('brain surgery').
  - History of bleeding or clotting disorder.
  - Current anticoagulant therapy such as warfarin.
  - Current drug or alcohol intoxication.
  - Age greater than or equal to 65 years.
  - Suspicion of non-accidental injury.
  - Irritability or altered behaviour ('easily distracted' 'not

  themselves' 'no concentration' 'no interest in things around them') particularly in infants and young children (that is, aged under 5 years).
  - Continuing concern by the helpline personnel about the diagnosis.
- In the absence of any of the factors listed in the two bullets above, the helpline should advise the injured person to seek medical advice from community services (for example, general practice) if any of the following factors are present.Ⓓ
  - Adverse social factors (for example, no one able to supervise the injured person at home).
  - Continuing concern by the injured person or their carer about the diagnosis.

Community health services and NHS minor injury clinics

- Community health services (general practice, paramedics, NHS walk-in centres, dental practitioners) and NHS minor injury clinics should refer patients who have sustained a head injury to a hospital A&E department, using the ambulance service if deemed necessary (see 'Transport to A&E' below), if any of the following is present.Ⓓ
  - GCS less than 15 at any time since injury.
  - Any loss of consciousness as a result of the injury.
  - Any focal neurological deficit since the injury (examples include problems understanding, speaking, reading or writing; decreased sensation; loss of balance; general weakness; visual changes; abnormal reflexes; and problems walking).
  - Any suspicion of a skull fracture or penetrating head injury since the injury (for example, clear fluid running from the ears or nose, black eye with no associated damage around the eyes, bleeding from one or both ears, new deafness in one or both ears, bruising behind one or both ears, penetrating injury signs, visible trauma to the scalp or skull of concern to the professional).
  - Amnesia for events before or after the injury. The assessment of amnesia will not be possible in pre-verbal

  children and is unlikely to be possible in any child aged under 5 years.
  - Persistent headache since the injury.
  - Any vomiting episodes since the injury (clinical judgement should be used regarding the cause of vomiting in those aged less than or equal to 12 years, and whether referral is necessary).
  - Any seizure since the injury.
  - Any previous cranial neurosurgical interventions.
  - A high-energy head injury (for example, pedestrian struck by motor vehicle, occupant ejected from motor vehicle, a fall from a height of greater than 1 metre or more than five stairs, diving accident, high-speed motor vehicle collision, rollover motor accident, accident involving motorized recreational vehicles, bicycle collision, or any other potentially high-energy mechanism). A lower threshold for height of falls should be used when dealing with infants and young children (that is, aged under 5 years).
  - History of bleeding or clotting disorder.
  - Current anticoagulant therapy such as warfarin.
  - Current drug or alcohol intoxication.
  - Age greater than or equal to 65 years.
  - Suspicion of non-accidental injury.
  - Continuing concern by the professional about the diagnosis.

- In the absence of factors listed in the bullet point above, the professional should consider referral to A&E if any of the following factors are present depending on their own judgement of severity. Ⓓ
  - Irritability or altered behaviour, particularly in infants and young children (that is, aged under 5 years).
  - Visible trauma to the head not covered above but still of concern to the professional.
  - Adverse social factors (for example, no one able to supervise the injured person at home).

  - Continuing concern by the injured person or their carer about the diagnosis.

TRANSPORT FROM COMMUNITY HEALTH SERVICES AND NHS MINOR INJURY CLINICS TO A&E AND PRE-HOSPITAL MANAGEMENT

Transport to A&E

- Patients referred from community health services and NHS minor injury clinics should be accompanied by a competent adult during transport to A&E.Ⓓ
- The referring professional should determine if an ambulance is required, based on the patient's clinical condition. If an ambulance is deemed not to be required, public transport and car are appropriate means of transport providing the patient is accompanied.Ⓓ
- The referring professional should inform the destination hospital (by phone) of the impending transfer and in non-emergencies a letter summarising signs and symptoms should be sent with the patient.Ⓓ

Pre-hospital management

The following principles should be adhered to in the immediate care of patients who have sustained a head injury.

- Patients who have sustained a head injury should initially be assessed and managed according to clear principles and standard practice as embodied in the advanced trauma life support (ATLS) system and for children the advanced paediatric life support (APLS) system.Ⓓ
- Paramedics should be fully trained in the use of the adult and paediatric versions of the GCS and its derived score.Ⓓ
- Paramedics should have some training in the detection of non-accidental injury and should pass this information to A&E personnel when the relevant signs and symptoms arise.Ⓓ
- The first priority for those administering immediate care is to treat first the greatest threat to life and avoid further harm.Ⓓ

- Patients who have sustained a head injury should be transported directly to a facility that has been identified as having the resources necessary to expeditiously assess and intervene to optimise outcome. It is expected that all acute hospitals accepting patients who have sustained a head injury should have these resources, and that these resources should be appropriate for the patient's age.Ⓓ
- Patients who have sustained a head injury and present with any of the following risk factors should have full cervical spine immobilisation attempted unless other factors prevent this:Ⓓ
  - GCS less than 15 at any time since the injury
  - neck pain or tenderness
  - focal neurological deficit
  - paraesthesia in the extremities
  - any other clinical suspicion of cervical spine injury.
- Cervical spine immobilisation should be maintained until full risk assessment (and imaging if deemed necessary) indicates it is safe to remove the immobilisation device.Ⓓ
- Standby calls to the destination A&E department should be made for all patients with a GCS less than or equal to 8, to ensure appropriately experienced professionals are available for their treatment and to prepare for imaging.Ⓓ
- An alerting call to the destination A&E department should be made for all patients with a GCS less than 15.Ⓓ

ASSESSMENT AND INVESTIGATION IN A&E

The main focus of A&E assessment for patients who have sustained a head injury should be the risk of clinically important brain injuries and injuries to the cervical spine and the consequent need for imaging. Due attention should also be paid to co-existing injuries and to other concerns the clinician may have (for example, non-accidental injury, possible non-traumatic aetiology such as seizure). Early imaging, rather than admission and observation for neurological deterioration, will reduce the time to detection of life-threatening complications and is associated with better outcomes.

A&E assessment

- The priority for all A&E patients is the stabilisation of airways, breathing and circulation (ABC) before attention to other injuries.Ⓓ
- Depressed conscious level should be ascribed to intoxication only after a significant brain injury has been excluded.Ⓓ
- All A&E clinicians involved in the assessment of patients with a head injury should be capable of assessing the presence or absence of the risk factors in the guidance on patient selection and urgency for imaging (head and cervical spine – see later recommendations). Training should be available as required to ensure that this is the case.Ⓓ
- Patients presenting to A&E with impaired consciousness (GCS less than 15) should be assessed immediately by a trained member of staff (for example, triage nurse).Ⓓ
- In patients with a GCS less than or equal to 8 there should be early involvement of an anaesthetist or critical care physician to provide appropriate airway management, as described in the section 'Transport of adults' below, and to assist with resuscitation.Ⓓ
- All patients presenting to A&E with a head injury should be assessed by triage by a trained member of staff within a maximum of 15 minutes of arrival at hospital. Part of this assessment should establish whether they are high risk or low risk for clinically important brain injury and/or cervical spine injury, using the guidance on patient selection and urgency for imaging (head and cervical spine – see later recommendations).Ⓓ
- Patients found to be high risk on triage for clinically important brain injury and/or cervical spine injury should be assessed within 10 minutes of triage by an A&E clinician. Part of this assessment should fully establish the need to request CT imaging of the head and/or imaging of the cervical spine. The guidance on patient selection and urgency for imaging (head and cervical spine) should form the basis for the final decision on imaging after discussion with the radiology department – see later recommendations.Ⓓ

- Patients with head injury who are discovered to be at low risk for clinically important brain injury and/or cervical spine injury on initial triage should be assessed within a further hour by an A&E clinician. Part of this assessment should fully establish the need to request CT imaging of the head and/or imaging of the cervical spine. The guidance on patient selection and urgency for imaging (head and cervical spine) should again form the basis for the final decision on imaging after discussion with the radiology department.Ⓓ
- In principle patients with head injury should not receive systemic analgesia until fully assessed so that an accurate measure of consciousness and other neurological signs can be made. Local anaesthetic should be delivered for fractured limbs or other painful injuries.Ⓓ
- Throughout the hospital episode, all care professionals should use a standard head injury proforma in their documentation when assessing and observing patients with head injury. A separate proforma for those under 16 years should be used. (Excellent proformas have been produced in previous guidelines from the Scottish Intercollegiate Guidelines Network and the Royal College of Surgeons of England. Areas to allow extra documentation should be included [for example, in cases of non-accidental injury]. Examples of proformas used for patients with head injury are provided on the NICE website www.nice.org.uk.)Ⓓ
- It is recommended that in-hospital observation of patients with a head injury, including all A&E observations, should only be conducted by professionals competent in the assessment of head injury.Ⓓ
- Patients who have returned to an A&E department within 48 hours of transfer to the community with any persistent complaint relating to the initial head injury should be seen by or discussed with a senior clinician experienced in head injuries, and considered for a CT scan.Ⓑ

Investigations for clinically important brain injuries

- The current primary investigation of choice for the detection of acute clinically important brain injuries is CT imaging of the head.Ⓐ

- For safety, logistic and resource reasons, MRI scanning is not currently indicated as the primary investigation for clinically important brain injury in patients who have sustained a head injury, although it is recognised that additional information of importance to the patient's prognosis can sometimes be detected using MRI.Ⓓ
- MRI is contraindicated in both head and cervical spine investigations unless there is absolute certainty that the patient does not harbour an incompatible device, implant or foreign body.Ⓓ
- There should be appropriate equipment for maintaining and monitoring the patient within the MRI environment and all staff involved should be aware of the dangers and necessary precautions for working near an MRI scanner.Ⓓ
- Skull X-rays have a role in the detection of non-accidental injury in children (see 'Investigations for non-accidental injury in children', below).Ⓓ
- Skull X-rays in conjunction with high-quality in-patient observation also have a role where CT scanning resources are unavailable.Ⓓ

SELECTION OF PATIENTS FOR CT IMAGING OF THE HEAD

- Patients who have sustained a head injury and present with any one of the following risk factors should have CT scanning of the head immediately requested.Ⓑ
  - GCS less than 13 at any point since the injury.
  - GCS equal to 13 or 14 at 2 hours after the injury.
  - Suspected open or depressed skull fracture.
  - Any sign of basal skull fracture (haemotympanum, 'panda' eyes, cerebrospinal fluid otorrhoea, Battle's sign).
  - Post-traumatic seizure.
  - Focal neurological deficit.
  - More than one episode of vomiting (clinical judgement should be used regarding the cause of vomiting in those aged 12 years or younger, and whether imaging is necessary).
  - Amnesia for greater than 30 minutes of events before impact. The assessment of amnesia will not be possible in

pre-verbal children and is unlikely to be possible in any child aged under 5 years.

- CT should also be immediately requested in patients with any of the following risk factors, provided they have experienced some loss of consciousness or amnesia since the injury:Ⓑ
  - Age greater than or equal to 65 years.
  - Coagulopathy (history of bleeding, clotting disorder, current treatment with warfarin).
  - Dangerous mechanism of injury (a pedestrian struck by a motor vehicle, an occupant ejected from a motor vehicle or a fall from a height of greater than 1 metre or five stairs). A lower threshold for height of falls should be used when dealing with infants and young children (that is, aged under 5 years).

IMAGING OF THE HEAD IN CHILDREN AND INFANTS

- Validated adult rules on imaging of the head may be safely used in children and infants.Ⓓ

URGENCY IN PERFORMING CT IMAGING OF THE HEAD

- CT imaging of the head should be performed (that is, imaging carried out and results analysed) within 1 hour of the request having been received by the radiology department in those patients where imaging is requested because of any of the following risk factors.Ⓑ
  - GCS less than 13 at any point since the injury.
  - GCS equal to 13 or 14 at 2 hours after the injury.
  - Suspected open or depressed skull fracture.
  - Any sign of basal skull fracture (haemotympanum, 'panda' eyes, cerebrospinal fluid otorrhoea, Battle's sign).
  - More than one episode of vomiting (clinical judgement should be used regarding the cause of vomiting in those aged less than or equal to 12 years, and whether imaging is necessary).
  - Age greater than or equal to 65 years, providing that some loss of consciousness or amnesia has been experienced.

  - Post-traumatic seizure.
  - Coagulopathy (history of bleeding, clotting disorder, current treatment with warfarin) providing that some loss of consciousness or amnesia has been experienced.
  - Focal neurological deficit.

- Patients who have any of the following risk factors and none of the risk factors listed in the bullet above should have their CT imaging performed within 8 hours of the injury (imaging should be performed immediately in these patients if they present 8 hours or more after their injury).Ⓑ
  - Amnesia for greater than 30 minutes of events before impact. The assessment of amnesia will not be possible in pre-verbal children and is unlikely to be possible in any child aged under 5 years.
  - Dangerous mechanism of injury (a pedestrian struck by a motor vehicle, an occupant ejected from a motor vehicle or a fall from a height of greater than 1 metre or five stairs) providing that some loss of consciousness or amnesia has been experienced. A lower threshold for height of falls should be used when dealing with infants and young children (that is, aged under 5 years).

Investigations for injuries to the cervical spine

- The current investigations of choice for the detection of injuries to the cervical spine are three-view plain radiographs of good technical quality.Ⓑ
- Where it is not possible to achieve the cervical spine views desired with X-ray, CT imaging is indicated.Ⓑ
- CT is also indicated if the plain film series is technically inadequate (for example, desired view unavailable), suspicious or definitely abnormal or if there is continued clinical suspicion of injury despite a normal study.Ⓑ
- CT imaging of the cervical spine should be considered if the patient is having other body areas scanned for head injury/multi-region trauma, and a definitive diagnosis of cervical spine injury is required urgently.Ⓑ
- As a minimum, CT should cover any areas of concern or uncertainty on plain film or clinical grounds.Ⓑ

- With modern multislice scanners the whole cervical spine can be scanned at high resolution with ease and multiplanar reformatted images generated rapidly. Facilities for multiplanar reformatting and interactive viewing should be available.Ⓑ
- MRI is indicated in the presence of neurological signs and symptoms referable to the cervical spine and if there is suspicion of vascular injury (for example, subluxation or displacement of the spinal column, fracture through foramen transversarium or lateral processes, posterior circulation syndromes).Ⓑ
- MRI may add important information about soft tissue injuries associated with bony injuries demonstrated by plain films and/or CT.Ⓑ
- MRI has a role in the assessment of ligamentous and disc injuries suggested by plain films, CT or clinical findings.Ⓑ
- In CT, the occipital condyle region should be routinely reviewed on 'bone windows' for patients who have sustained a head injury. Reconstruction of standard head images onto a high-resolution bony algorithm is readily achieved with modern CT scanners.Ⓑ
- In patients who have sustained high-energy trauma or are showing signs of lower cranial nerve palsy, the results of initial imaging should be considered and particular attention should be paid to the region of the foramen magnum. If necessary, additional high-resolution imaging for coronal and sagittal reformatting should be performed while the patient is on the scanner table.Ⓑ

SELECTION OF PATIENTS FOR IMAGING OF THE CERVICAL SPINE

- Patients with any one of the following risk factors should have three-view radiograph imaging of the cervical spine immediately requested.Ⓐ
  - GCS less than 15 at the time of assessment.
  - Paraesthesia in the extremities.
  - Focal neurological deficit.
  - Not possible to test for range of motion in the neck (safe assessment of range of motion can be performed with the

  following: simple rear-end motor vehicle collision, sitting position in A&E, ambulatory at any time since injury, delayed onset of neck pain, absence of midline cervical spine tenderness).
  - Patient not able to actively rotate neck to 45 degrees to the left and right (if assessment is possible).

- Cervical spine imaging should also be immediately requested in the patients with the following risk factors provided they have some neck pain or tenderness.Ⓐ
  - Age greater than or equal to 65 years.
  - Dangerous mechanism of injury (fall from greater than 1 metre or five stairs; axial load to head for example, diving; high-speed motor vehicle collision greater than 65 miles per hour; rollover motor accident; ejection from a motor vehicle; accident involving motorised recreational vehicles; bicycle collision). A lower threshold for height of falls should be used when dealing with infants and young children (that is, aged under 5 years).

CERVICAL SPINE IMAGING OF INFANTS AND CHILDREN

- Children aged 10 years or more can be treated as adults for the purposes of cervical spine imaging.Ⓓ
- In children under 10 years, because of the increased risks associated with irradiation, particularly to the thyroid gland, and the generally lower risk of significant spinal injury, CT of the cervical spine should only be used in exceptional circumstances (for example, cases where there is a strong suspicion of injury despite normal plain films, or cases where there is a strong suspicion of injury and plain films are inadequate).Ⓓ
- Children under 10 years should receive anterior/posterior and lateral views without an anterior/posterior peg view.Ⓓ
- Abnormalities or uncertainties in those under 10 years should be clarified by CT imaging. Minor trauma associated with subsequent torticollis results in plain films that are almost uninterpretable and CT is very helpful in this situation.Ⓓ

URGENCY IN PERFORMING CERVICAL SPINE IMAGING

- Imaging of the cervical spine should be performed within 1 hour of a request having been received by the radiology department. Where a request for urgent head CT (that is, within 1 hour) has also been received, the cervical spine imaging should be carried out immediately.Ⓓ

USING ADULT RULES WITH INFANTS AND CHILDREN

- As the best evidence on selecting patients with head injury for imaging exists for adults, and children and infants have a lower risk of brain and cervical spine injury than adults, validated adult rules on imaging of the head and cervical spine may be safely used in children and infants.Ⓓ

Investigations for non-accidental injury in children

- Due to the distinct pattern of injuries involved, skull X-ray as part of a series of plain X-rays (skeletal survey), along with other well-established examinations (for example, ophthalmoscopic examination for retinal haemorrhage; examination for pallor, anaemia, tense fontanelle) and investigations (for example, CT, MRI), has a role in detecting non-accidental head injuries in children (that is, those aged under 12 years).Ⓓ

Radiation exposure management

- In line with good radiation exposure practice every effort should be made to minimise radiation dose during imaging of the head and cervical spine, while ensuring that image quality and coverage is sufficient to achieve an adequate diagnostic study.Ⓓ
- CT imaging of the cervical spine should only be used in exceptional circumstances in children aged under 10 years.Ⓓ

Involving the neurosurgeon

- The care of all patients with new, surgically significant abnormalities on imaging should be discussed with a neurosurgeon. The definition of 'surgically significant' should be developed by local neurosurgical centres and agreed with referring hospitals. An example of a neurosurgical referral letter is provided on the NICE website www.nice.org.uk.Ⓓ

- Regardless of imaging, other reasons for discussing a patient's care plan with a neurosurgeon include:Ⓓ
  - persisting coma (GCS less than or equal to 8) after initial resuscitation
  - unexplained confusion which persists for more than 4 hours
  - deterioration in GCS score after admission (greater attention should be paid to motor response deterioration)
  - progressive focal neurological signs
  - a seizure without full recovery
  - definite or suspected penetrating injury
  - a cerebrospinal fluid leak.

ADMISSION

- The following patients meet the criteria for admission to hospital following a head injury.Ⓓ
  - Patients with new, clinically significant abnormalities on imaging.
  - Patients who have not returned to GCS equal to 15 after imaging, regardless of the imaging results.
  - When a patient fulfils the criteria for CT scanning but this cannot be done within the appropriate period, either because CT is not available or because the patient is not sufficiently co-operative to allow scanning.
  - Continuing worrying signs of concern to the clinician (for example, persistent vomiting, severe headaches).
  - Other sources of concern to the clinician (for example, drug or alcohol intoxication, other injuries, shock, suspected non-accidental injury, meningism, cerebrospinal fluid leak).
- Some patients may require an extended period in a recovery setting due to the use of sedation or general anaesthetic during CT imaging. These patients should not normally require admission.Ⓓ

- Patients with multiple injuries should be admitted under the care of the team that is trained to deal with their most severe and urgent problem.Ⓓ
- In circumstances where a patient with a head injury requires hospital admission, it is recommended that the patient only be admitted under the care of a consultant who has been trained in the management of this condition during his/her higher specialist training.Ⓓ
- It is recommended that in-hospital observation of patients with a head injury should only be conducted by professionals competent in the assessment of head injury.Ⓓ

TRANSFER FROM SECONDARY TO TERTIARY CARE SETTINGS

Transfer of adults

- Local guidelines on the transfer of patients with head injuries should be drawn up between the referring hospital trusts and the neurosurgical unit and should be consistent with established national guidelines. Details of the transfer of the responsibility for patient care should also be agreed.Ⓓ
- There should be a designated consultant in the referring hospital with responsibility for establishing arrangements for the transfer of patients with head injuries to a neurosurgical unit and another consultant at the neurosurgical unit with responsibility for establishing arrangements for communication with referring hospitals and for receipt of patients transferred.Ⓓ
- Patients with head injuries should be accompanied by a doctor with at least 2 years' experience in an appropriate specialty (usually anaesthesia). They should be familiar with the pathophysiology of head injury, the drugs and equipment they will use, working in the confines of an ambulance (or helicopter if appropriate) and have received supervised training in the transfer of patients with head injuries. They should have an adequately trained assistant. They should be provided with appropriate clothing for the transfer, medical indemnity and personal insurance.Ⓓ
- The transfer team should be provided with a means of

communication with their base hospital and the neurosurgical unit during the transfer. A portable phone may be suitable providing it is not used in close proximity (that is, within 1 metre) of medical equipment prone to electrical interference (for example, infusion pumps).Ⓓ

- Thorough resuscitation and stabilisation of the patient should be completed before transfer to avoid complications during the journey. A patient persistently hypotensive despite resuscitation should not be transported until all possible causes of the hypotension have been identified and the patient stabilised.Ⓓ
- All patients with a GCS less than or equal to 8 requiring transfer to tertiary care should be intubated and ventilated as should any patients with the indications detailed in the bullet below.Ⓓ
- Intubation and ventilation should be used immediately in the following circumstances.Ⓓ
  - Coma – not obeying commands, not speaking, not eye opening (that is, GCS less than or equal to 8).
  - Loss of protective laryngeal reflexes.
  - Ventilatory insufficiency as judged by blood gases: hypoxaemia (PaO_2 less than 9 kPa on air or less than 13 kPa on oxygen) or hypercarbia ($PaCO_2$ greater than 6 kPa).
  - Spontaneous hyperventilation (causing $PaCO_2$ less than 3.5 kPa).
  - Respiratory arrhythmia.
- Intubation and ventilation should be used before the start of the journey in the following circumstances.Ⓓ
  - Significantly deteriorating conscious level, even if not coma.
  - Bilateral fractured mandible.
  - Copious bleeding into mouth (for example, from skull base fracture).
  - Seizures.
- An intubated patient should be ventilated with muscle

relaxation and appropriate sedation and analgesia. Aim for a PaO_2 greater than 13 kPa, $PaCO_2$ 4.5 to 5.0 kPa unless there is clinical or radiological evidence of raised intracranial pressure when more aggressive hyperventilation is justified.Ⓓ

- Education, training and audit are crucial to improving standards of transfer; appropriate time and funding should be provided.Ⓓ
- Carers and relatives should have as much access to the patient as is practical during transfer and be fully informed on the reasons for transfer and the transfer process.Ⓓ

Transfer of children

- The recommendations above were written for adults but the principles apply equally to children and infants, providing that the paediatric modification of the Glasgow Coma Scale is used.Ⓓ
- Service provision in the area of paediatric transfer to tertiary care should also follow the principles outlined in the National Service Framework for Paediatric Intensive Care. These do not conflict with the principles outlined above.Ⓓ
- Transfer of a child or infant to a specialist neurosurgical unit should be undertaken by staff experienced in the transfer of critically ill children.Ⓓ
- Families should have as much access to their child as is practical during transfer and be fully informed on the reasons for transfer and the transfer process.Ⓓ

OBSERVATION OF ADMITTED PATIENTS

Training in observation

- Medical, nursing and other staff caring for patients with head injury admitted for observation should all be capable of performing the observations listed in 'Minimum documented observations' and 'Patient changes requiring review while under observation' below.Ⓓ
- The acquisition and maintenance of observation and recording skills requires dedicated training and this should be available to all relevant staff.Ⓓ

- Specific training is required for the observation of infants and young children.Ⓓ

Minimum documented observations

- For patients admitted for head injury observation the minimum acceptable documented neurological observations are: GCS; pupil size and reactivity; limb movements; respiratory rate; heart rate; blood pressure; temperature; blood oxygen saturation.Ⓓ

Frequency of observations

- Observations should be performed and recorded on a half-hourly basis until GCS equal to 15 has been achieved. The minimum frequency of observations for patients with GCS equal to 15 should be as follows, starting after the initial assessment in A&E:Ⓓ
  - half-hourly for 2 hours
  - then 1 hourly for 4 hours
  - then 2 hourly thereafter.
- Should the patient with GCS equal to 15 deteriorate at any time after the initial 2-hour period, observations should revert to half-hourly and follow the original frequency schedule.Ⓓ

Observation of children and infants

- Observation of infants and young children (that is, aged under 5 years) is a difficult exercise and therefore should only be performed by units with staff experienced in the observation of infants and young children with a head injury. Infants and young children may be observed in normal paediatric observation settings, as long as staff have the appropriate experience.Ⓓ

Patient changes requiring review while under observation

- Any of the following examples of neurological deterioration should prompt urgent reappraisal by the supervising doctor.Ⓓ
  - Development of agitation or abnormal behaviour.

  - A sustained (that is, for at least 30 minutes) drop of one point in GCS level (greater weight should be given to a drop of one point in the motor score of the GCS).
  - Any drop of greater than two points in GCS level regardless of duration or GCS sub-scale.
  - Development of severe or increasing headache or persisting vomiting.
  - New or evolving neurological symptoms or signs such as pupil inequality or asymmetry of limb or facial movement.

- To reduce inter-observer variability and unnecessary referrals, a second member of staff competent to perform observation should confirm deterioration before involving the supervising doctor. This confirmation should be carried out immediately. Where a confirmation cannot be performed immediately (for example, no staff member available to perform the second observation) the supervising doctor should be contacted without the confirmation being performed.Ⓓ

IMAGING FOLLOWING CONFIRMED PATIENT DETERIORATION

- An immediate CT scan should be considered in patients confirmed as having any of the changes noted as examples of neurological deterioration above.Ⓓ

FURTHER IMAGING IF GCS EQUAL TO 15 NOT ACHIEVED AT 24 HOURS

- In the case of a patient who has had a normal CT scan but who has not achieved GCS equal to 15 after 24 hours observation, a further CT scan or MRI scanning should be considered and discussed with the radiology department.Ⓓ

DISCHARGE

General

DISCHARGE AND GCS STATUS

- No patients presenting with head injury should be transferred to the community until they have achieved GCS equal to 15, or normal consciousness in infants and young children as assessed by the paediatric version of the GCS.Ⓓ

DISCHARGE ADVICE

- All patients with any degree of head injury who are deemed safe for appropriate transfer to the community from A&E or the observation ward should receive verbal advice and a written head injury advice card. The details of the card should be discussed with the patients and their carers. If necessary (for example, patients with literacy problems, visual impairment or speaking languages without a written format), other formats (for example, tapes) should be used to communicate this information. Communication in languages other than English should also be facilitated.Ⓓ
- The risk factors outlined in the card should be the same as those used in the initial community setting to advise patients on A&E attendance. Patients and carers should also be alerted to the possibility that some patients may make a quick recovery, but go on to experience delayed complications. Instructions should be included on contacting community services in the event of delayed complications.Ⓓ
- Patients who presented to A&E with drug or alcohol intoxication and are now fit for discharge should receive information and advice on alcohol or drug misuse.Ⓓ
- Suggested written advice cards for patients and carers are provided on the NICE website www.nice.org.uk..Ⓓ

DISCHARGE OF PATIENTS WITH NO CARER AT HOME

- All patients with any degree of head injury should only be transferred to their home if it is certain that there is somebody suitable at home to supervise the patient. Patients with no carer at home should only be discharged if suitable supervision arrangements have been organised, or when the risk of late complications is deemed negligible.Ⓓ

Discharge of specific patient groups

LOW-RISK PATIENTS WITH GCS EQUAL TO 15

- If CT is not indicated on the basis of history and examination the clinician may conclude that the risk of clinically important brain injury to the patient is low enough to warrant transfer to the community, as long as no other factors that would warrant a hospital admission are present (for example, drug or alcohol intoxication, other injuries, shock, suspected non-accidental injury, meningism, cerebrospinal fluid leak) and there are appropriate support structures for safe transfer to the community and for subsequent care (for example, competent supervision at home).Ⓓ

PATIENTS WITH NORMAL IMAGING OF THE HEAD

- After normal imaging of the head, the clinician may conclude that the risk of clinically important brain injury requiring hospital care is low enough to warrant transfer to the community, as long as the patient has returned to GCS equal to 15, and no other factors that would warrant a hospital admission are present (for example, drug or alcohol intoxication, other injuries, shock, suspected non-accidental injury, meningism, cerebrospinal fluid leak) and there are appropriate support structures for safe transfer to the community and for subsequent care (for example, competent supervision at home).Ⓓ

PATIENTS WITH NORMAL IMAGING OF THE CERVICAL SPINE

- After normal imaging of the cervical spine the clinician may conclude that the risk of injury to the cervical spine is low enough to warrant transfer to the community, as long as the patient has returned to GCS equal to 15 and their clinical examination is normal, and no other factors that would warrant a hospital admission are present (for example, drug or alcohol intoxication, other injuries, shock, suspected nonaccidental injury, meningism, cerebrospinal fluid leak) and there are appropriate support structures for safe transfer to the community and for subsequent care (for example, competent supervision at home).Ⓓ

PATIENTS ADMITTED FOR OBSERVATION

- Patients admitted after a head injury may be transferred to the community after resolution of all significant symptoms and signs providing they have suitable supervision arrangements at home.Ⓓ

PATIENTS AT RISK OF NON-ACCIDENTAL INJURY

- No infants or children presenting with head injuries that require imaging of the head or cervical spine should be transferred to the community until assessed by a clinician experienced in the detection of non-accidental injury.Ⓓ
- It is expected that all personnel involved in the triage and assessment of infants and children with head injury should have some training in the detection of non-accidental injury.Ⓓ

Outpatient appointments

- Every patient who has undergone imaging of the head and/or been admitted to hospital (that is, those initially deemed to be at high risk for clinically important brain injury) should be referred to their GP for follow up as routine within a week after discharge.Ⓓ
- When a person who has undergone imaging of the head and/or been admitted to hospital experiences persisting problems, there should be an opportunity available for referral from primary care to an out-patient appointment with a professional trained in assessment and management of sequelae of brain injury (for example, clinical psychologist, neurologist, neurosurgeon, specialist in rehabilitation medicine).Ⓓ

Advice about long-term problems and support services

- All patients and their carers should be made aware of the possibility of long-term symptoms and disabilities following head injury and should be made aware of the existence of services that they could contact should they experience longterm problems. Details of support services should be included on patient discharge advice cards. Patients should also be advised to contact their doctor about these problems.Ⓓ

Communication with community services

A communication (letter or email) should be generated for all patients who have attended A&E with a head injury, and sent to the patient's GP within 1 week of the end of the hospital episode. This letter should include details of the clinical history and examination. This letter should be open to the person or their carer, or a copy should be given to them.Ⓓ

- A communication (letter or email) should be generated for all children who received head or cervical spine imaging, and sent to the relevant community paediatrician and school medical officer within 1 week of the end of the hospital episode. This letter should include details of the clinical history and examination.Ⓓ
- A communication (letter or email) should be generated for all infants who received head or cervical spine imaging, and sent to the relevant community paediatrician and health visitor within 1 week of the end of the hospital episode. This letter should include details of the clinical history and examination.Ⓓ

Mental health

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TECHNOLOGY APPRAISAL

Computerised cognitive behavioural therapy for anxiety and depression

Issue date – October 2002 **Review date** – September 2003

Current research suggests that the delivery of cognitive behavioural therapy via a computer interface (CCBT) may be of value in the management of anxiety and depressive disorders. This evidence is, however, an insufficient basis on which to recommend the general introduction of this technology into the NHS.

To establish the contribution and place of CCBT in the management of anxiety and depressive disorders, including its role within 'stepped care' approaches, the NHS should consider supporting an independent programme of research into CCBT, including carefully monitored pilot implementation projects. The research should include investigations into user preferences, suitability, needs and educational/cultural characteristics.

CLINICAL GUIDELINE

Core interventions in the treatment and management of schizophrenia in primary and secondary care

Issue date – December 2002 **Review date** – December 2006

Developed by the National Collaborating Centre for Mental Health.

GRADING SCHEME

All evidence was classified according to an accepted hierarchy of evidence that is adapted from the US Agency for Healthcare Policy and Research Classification (see Table 1). Recommendations were then graded A to C based on the level of associated evidence or noted as a good practice point (see Table 2) – this grading scheme is based on a scheme formulated by the Clinical Outcomes Group of the NHS Executive (1996). 'NICE 2002' indicates that the recommendation is from the NICE technology appraisal of atypical antipsychotic drugs (see

'Newer (atypical) antipsychotic drugs for schizophrenia' in this section).

Hierarchy of evidence

Table 1 Levels of evidence

Level	Type of evidence
Ia	evidence obtained from a single large randomised trial or a meta-analysis of at least three randomised controlled trials
Ib	evidence obtained from a small randomised controlled trial or a meta-analysis of less than three randomised controlled trials
IIa	evidence obtained from at least one well-designed controlled study without randomisation
IIb	evidence obtained from at least one other well-designed quasi-experimental study
III	evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies
IV	evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

Adapted from Eccles M, Mason J (2001) How to develop cost-conscious guidelines. Health Technology Assessment 5: 16.

Table 2 Grading of recommendations

Grade	Source
Ⓐ	at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia and Ib) without extrapolation
Ⓑ	well-conducted clinical studies but no randomised clinical trials on the topic of recommendation (evidence levels IIa, IIb, III), or with extrapolation from level I evidence
Ⓒ	expert committee reports or opinions and/or clinical experiences of respected authorities. This grading indicates that directly applicable clinical studies of good quality are absent (evidence level IV), or with extrapolation from higher levels of evidence

Table 2 Grading of recommendations (continued)

Grade	Source
NICE 2002	recommendation drawn from the NICE technology appraisal of the use of the newer (atypical) antipsychotic drugs for schizophrenia
Good Practice Point (GPP)	recommended good practice based on the clinical experience of the Guideline Development Group

Based on a scheme from: NHS Executive. Clinical Guidelines: Using Clinical Guidelines to Improve Patient Care Within the NHS. London: 1996

For the purposes of this guideline, the treatment and management of schizophrenia has been divided into three phases:

- initiation of treatment at the first episode
- acute phase
- promoting recovery.

The guideline makes good practice points and recommendations for psychological, pharmacological and service-level interventions in the three phases of care in both primary care and secondary mental health services. Drugs considered in this guideline are restricted to those licensed for use in the UK prior to May 2002, and the psychological treatments dealt with here are for use in addition to antipsychotic medication.

The first section that follows contains the good practice points and recommendations that apply across all three phases of care.

CARE ACROSS ALL PHASES

Optimism

The effects of schizophrenia on a person's life experience and opportunities are considerable; service users and carers need help and support to deal with their future and to cope with the changes the illness brings.

- Health professionals should work in partnership with service users and carers, offering help, treatment and care in an atmosphere of hope and optimism. GPP

Getting help early

For most people experiencing a schizophrenic breakdown, the level of distress, anxiety and subjective confusion, especially during first episodes, leads to difficulty in accessing services.

- Service users and their relatives seeking help should be assessed and receive treatment at the earliest possible opportunity. GPP

Assessment

The purpose of this guideline is to help improve the experience and outcomes of care for people with schizophrenia. These outcomes include the degree of symptomatic recovery, quality of life, degree of personal autonomy, ability and access to work, stability and quality of living accommodation, degree and quality of social integration, degree of financial independence and the experience and impact of side effects.

- The assessment of needs for health and social care for people with schizophrenia should, therefore, be comprehensive and address medical, social, psychological, occupational, economic, physical and cultural issues. GPP

Working in partnership with service users and carers

- Health professionals involved in the routine treatment and management of schizophrenia should take time to build a supportive and empathic relationship with service users and carers; this should be regarded as an essential element of the routine care offered. GPP

The families of people with schizophrenia often play an essential part in the treatment and care of their relative, and with the right support and help, can positively contribute to promoting recovery. Parents of people with schizophrenia often feel to blame, either because they have ‘passed on’ the genes causing schizophrenia, or because they are ‘bad parents’.

- Clear and intelligible information should be made available to service users and their families about schizophrenia and its possible causes, and about the possible role families can have in promoting recovery and reducing relapse. GPP

Consent

Whatever treatments are offered, it is essential to engage the service user in a collaborative, trusting and caring working relationship at the earliest opportunity. Professionals should take into full account the particular nature of schizophrenia: namely, that the illness may affect people's ability to make judgments, to recognise that they are ill, to comprehend clearly what professionals might say to them and to make informed decisions about their treatment and care.

- Health professionals should make all efforts necessary to ensure that a service user can give meaningful and properly informed consent before treatment is initiated, giving adequate time for discussion and the provision of written information. GPP

Providing good information and mutual support

- Health professionals should provide accessible information about schizophrenia and its treatment to service users and carers; this should be considered an essential part of the routine treatment and management of schizophrenia. GPP
- In addition to the provision of good-quality information, families and carers should be offered the opportunity to participate in family or carer support programmes, where these exist. GPP

Language and culture

- When talking to service users and carers, health professionals should avoid using clinical language or keep it to a minimum. Where clinical language is used, service users and carers should have access to written explanations. GPP
- All services should provide written material in the language of the service user, and interpreters should be sought for people who have difficulty in speaking English. GPP

Advance directives

- Although there are limitations with advance directives regarding the choice of treatment for individuals with schizophrenia, it is recommended that they are developed and documented in individuals' care programmes whenever possible. NICE 2002

- When advance directives have been agreed, copies should be placed in primary-care and secondary-care case notes/care plans, and copies given to the service user and his or her care coordinator. If appropriate, and subject to agreement with the service user, a copy should be given to his or her carer. GPP

INITIATION OF TREATMENT (FIRST EPISODE)

Early referral

It is most likely that the first point of contact for people who may be developing schizophrenia for the first time will be a primary care professional. Rapid identification, early referral and good liaison with secondary services are a priority.

- In primary care, all people with suspected or newly diagnosed schizophrenia should be referred urgently to secondary mental health services for assessment and development of a care plan. If there is a presumed diagnosis of schizophrenia then part of the urgent assessment should include an early assessment by a consultant psychiatrist. GPP

Early intervention services

- Because many people with actual or possible schizophrenia have difficulty in getting help, treatment and care at an early stage, it is recommended that early intervention services are developed to provide the correct mix of specialist pharmacological, psychological, social, occupational and educational interventions at the earliest opportunity. GPP
- Where the needs of the service user and/or carer exceed the capacity of early intervention services, referral to crisis resolution and home treatment teams, acute day hospitals or inpatient services should be considered. GPP

Early treatment

- Where there are acute symptoms of schizophrenia, the GP should consider starting atypical antipsychotic drugs at the earliest opportunity – before the individual is seen by a psychiatrist, if necessary. Wherever possible, this should be following discussion with a psychiatrist and referral should be a matter of urgency. GPP

Pharmacological intervention

- It is recommended that the oral atypical antipsychotic drugs amisulpride, olanzapine, quetiapine, risperidone and zotepine are considered in the choice of first-line treatments for individuals with newly diagnosed schizophrenia. NICE 2002
- Atypical antipsychotics at the lower end of the standard dose range are the preferred treatments for a person experiencing a first episode of schizophrenia. Ⓒ

Second opinion

After the first episode, many people are unsure about their diagnosis and may need help with this.

- A decision by the service user, and carer where appropriate, to seek a second opinion on the diagnosis should be supported, particularly in view of the considerable personal and social consequences of being diagnosed with schizophrenia. GPP

TREATMENT OF THE ACUTE EPISODE

Service-level interventions

The services most likely to help people who are acutely ill include crisis resolution and home treatment teams, early intervention teams, community mental health teams and acute day hospitals. If these services are unable to meet the needs of a service user, or if the Mental Health Act is used, inpatient treatment may prove necessary for a period of time. Whatever services are available, a broad range of social, group and physical activities are essential elements of the services provided.

- Community mental health teams are an acceptable way of organising community care and may have the potential for effectively co-ordinating and integrating other community based teams providing services for people with schizophrenia. However, there is insufficient evidence of their advantages to support a recommendation which precludes or inhibits the development of alternative service configurations. Ⓒ
- Crisis resolution and home treatment teams should be used as a means to manage crises for service users, and as a

means of delivering high-quality acute care. In this context, teams should pay particular attention to risk monitoring as a high-priority routine activity. Ⓑ

- Crisis resolution and home treatment teams should be considered for people with schizophrenia who are in crisis to augment the services provided by early intervention services and assertive outreach teams. Ⓒ
- Crisis resolution and home treatment teams should be considered for people with schizophrenia who may benefit from early discharge from hospital following a period of inpatient care. Ⓒ
- Acute day hospitals should be considered as a clinical and cost-effective option for the provision of acute care, both as an alternative to acute admission to inpatient care and to facilitate early discharge from inpatient care. Ⓐ
- Social, group and physical activities are an important aspect of comprehensive service provision for people with schizophrenia as the acute phase recedes, and afterwards. All care plans should record the arrangements for social, group and physical activities. GPP

Pharmacological interventions

During an acute episode, antipsychotic drugs are necessary. Wherever possible, service users should make an informed choice as to the antipsychotic they prefer. If a service user is unable to make his or her preference known, an atypical should be prescribed. It is best to use a single drug, using doses within the *British National Formulary* (*BNF*) dose range and not to use high or loading doses. Clinical response and side effects should be monitored routinely and regularly. If, with conventional antipsychotics, side effects are troublesome or symptom control is inadequate, an atypical should be offered. During an acute episode, some service users become behaviourally disturbed and may need rapid tranquillisation. The recommendations for this can be found in the 'Rapid tranquillisation' section below.

- The choice of antipsychotic drug should be made jointly by the individual and the clinician responsible for treatment based on an informed discussion of the relative benefits of the drugs and their side-effect profiles. The individual's advocate or carer should be consulted where appropriate. NICE 2002

- Antipsychotic therapy should be initiated as part of a comprehensive package of care that addresses the individual's clinical, emotional and social needs. The clinician responsible for treatment and key worker should monitor both therapeutic progress and tolerability of the drug on an ongoing basis. Monitoring is particularly important when individuals have just changed from one antipsychotic to another. NICE 2002
- The dosage of conventional antipsychotic medication for an acute episode should be in the range of 300–1000 mg chlorpromazine equivalents per day for a minimum of 6 weeks. Reasons for dosage outside this range should be justified and documented. The minimum effective dose should be used. Ⓒ
- In the treatment of the acute episode for people with schizophrenia, massive loading doses of antipsychotic medication, referred to as 'rapid neuroleptization', should not be used. Ⓒ
- The oral atypical antipsychotic drugs (amisulpride, olanzapine, quetiapine, risperidone, zotepine) should be considered as treatment options for individuals currently receiving conventional antipsychotic drugs who, despite adequate symptom control, are experiencing unacceptable side effects, and for those in relapse who have previously experienced unsatisfactory management or unacceptable side effects with conventional antipsychotic drugs. The decision as to what are unacceptable side effects should be taken following discussion between the patient and the clinician responsible for treatment. NICE 2002
- When full discussion between the clinician responsible for treatment and the individual concerned is not possible, in particular in the management of an acute schizophrenic episode, the oral atypical drugs should be considered as the treatment options of choice because of the lower potential risk of extrapyramidal symptoms (EPS). In these circumstances, the individual's carer or advocate should be

consulted where possible and appropriate. Although there are limitations with advance directives regarding the choice of treatment for individuals with schizophrenia, it is recommended that they are developed and documented in individuals' care programmes whenever possible. NICE 2002

- It is not recommended that, in routine clinical practice, individuals change to one of the oral atypical antipsychotic drugs if they are currently achieving good control of their condition without unacceptable side effects with conventional antipsychotic drugs. NICE 2002
- Antipsychotic drugs, atypical or conventional, should not be prescribed concurrently, except for short periods to cover changeover. Ⓒ
- When prescribed chlorpromazine, individuals should be warned of a potential photosensitive skin response as this is an easily preventable side effect. Ⓑ
- Where a potential to cause weight gain or diabetes has been identified (and/or included in the Summary of Product Characteristics) for the atypical antipsychotic being prescribed, there should be routine monitoring in respect of these potential risks. Ⓑ

Early post-acute period

Towards the end of an acute episode of schizophrenia, service users should be offered help to better understand the period of illness, and given the opportunity to write their account in their notes. Carers may also need help in understanding the experience. Assessment for further help to minimise disability, reduce risk and improve quality of life should be routinely undertaken during recovery from the acute phase. In particular, psychological and family help, contingency planning and identifying local resources/services are important. Advice about drug treatments to maintain recovery is also important.

SERVICE USER FOCUS

- Consideration should be given, where practicable, to encouraging service users to write their account of their illness in their notes. GPP
- Psychoanalytic and psychodynamic principles may be considered to help health professionals to understand the

experience of individual service users and their interpersonal relationships. GPP

ASSESSMENT

The purpose of this guideline is to help improve the experience and outcomes of care for people with schizophrenia. These outcomes include the degree of symptomatic recovery, quality of life, degree of personal autonomy, ability and access to work, stability and quality of living accommodation, degree and quality of social integration, degree of financial independence and the experience and impact of side effects.

- The assessment of needs for health and social care for people with schizophrenia should, therefore, be comprehensive and address medical, social, psychological, occupational, economic, physical and cultural issues. GPP

PSYCHOLOGICAL TREATMENTS

- Cognitive behavioural therapy (CBT) should be available as a treatment option for people with schizophrenia. Ⓐ
- Family interventions should be available to the families of people with schizophrenia who are living with or who are in close contact with the service user. Ⓐ
- Counselling and supportive psychotherapy are not recommended as discrete interventions in the routine care of people with schizophrenia where other psychological interventions of proven efficacy are indicated and available. However, service user preferences should be taken into account, especially if other more efficacious psychological treatments are not locally available. Ⓒ

MEDICATION ADVICE

- Given the high risk of relapse following an acute episode, the continuation of antipsychotic drugs for up to 1 to 2 years after a relapse should be discussed with service users, and carers where appropriate. GPP
- Withdrawal from antipsychotic medication should be undertaken gradually whilst regularly monitoring signs and symptoms for evidence of potential relapse. GPP
- Following withdrawal from antipsychotic medication, monitoring for signs and symptoms of potential relapse

should continue for at least 2 years after the last acute episode. GPP

PROMOTING RECOVERY

There are a number of options for promoting and maintaining recovery. The general principles for all phases apply equally in this situation. Early intervention to provide early additional treatment and care should the need arise remains important.

Primary care

Primary care professionals have an important part to play in the physical and mental health care of people with schizophrenia. They are best placed to monitor the physical health of people with schizophrenia and should do so regularly. Case registers will be an important means of doing so. In addition, primary care workers should monitor the mental health and treatment of their service users, work closely with secondary services and refer before crises arise wherever possible.

- The organisation and development of practice case registers for people with schizophrenia is recommended as an essential step in monitoring the physical and mental health of people with schizophrenia in primary care. GPP
- GPs and other primary health workers should regularly monitor the physical health of people with schizophrenia registered with their practice. The frequency of checks will be a clinical decision made jointly between the service user and clinician. The agreed frequency should be recorded in the patient's notes. GPP
- Physical health checks should pay particular attention to endocrine disorders, such as diabetes and hyperprolactinaemia, cardiovascular risk factors, such as blood pressure and lipids, side effects of medication, and lifestyle factors such as smoking. These must be recorded in the notes. GPP
- The decision to re-refer a service user from primary care to mental health services is a complex clinical judgment that should take account of the views of the service user and, where appropriate, carers. Issues of confidentiality should be respected when involving carers. Referral may be considered

in a number of circumstances, but particular factors indicating referral include the following: GPP

- where treatment adherence is a problem, referral is usually indicated
- a poor response to treatment would make referral a higher priority
- if co-morbid substance misuse is suspected, referral is indicated
- if the level of risk to self or others is increased, referral to secondary services is indicated
- when a person with schizophrenia first joins a GP practice list, referral to secondary services for assessment and care programming is indicated, subject to the full agreement of the service user.

Secondary services

Secondary services should undertake regular and full assessment of the mental and physical health of their service users, addressing all the issues relevant to a person's quality of life and well-being. When a service user chooses not to receive physical care from his or her GP, this should be monitored by doctors in secondary care. Carers should be contacted routinely, subject to the agreement of the service user and should be provided with a care plan. The possible presence of co-morbid conditions, including substance and alcohol misuse or physical illness, or the existence of a forensic history, will necessitate the development of treatment and care plans outside the scope of this guideline. Nevertheless, full assessment of these issues should be included.

- A full assessment of health and social care needs should be undertaken regularly, including assessment of accommodation and quality of life, the frequency of which should be based upon clinical need, and following discussion with the service user. The agreed frequency of assessment should be documented in the care plan. GPP

The higher physical morbidity and mortality of service users with schizophrenia should be considered in all assessments. Whilst this would normally be expected to be the role of primary care services, secondary care services should nevertheless monitor these matters where they believe a service user may have little regular contact with primary care.

- Primary and secondary care services, in conjunction with the service user, should jointly identify which service will take responsibility for assessing and monitoring the physical health care needs of service users. This should be documented in both primary and secondary care notes/care plans and clearly recorded by care co-ordinators for those on the enhanced care programme approach (CPA). GPP
- Moreover, all non-professional carers who provide regular care for a person on CPA should have an assessment of their caring, physical and mental health needs, at a frequency agreed in conjunction with the carer and recorded in their own (carer) care plan. GPP

Service interventions

The range of services needed for people with schizophrenia are diverse and need to be tailored to individual circumstances and current local resources. However, some people with schizophrenia have high needs for care and tend to be lost from ordinary services. Assertive outreach teams (or assertive community treatment – ACT) are an effective way of helping to meet those needs and are better at staying in touch than ordinary services. Also, most people with schizophrenia will need rapid access to help in crises. Services need to plan how to best deliver help and treatment ensuring that teams are functionally integrated.

- Assertive outreach teams should be provided for people with serious mental disorders including people with schizophrenia. Ⓑ
- Assertive outreach teams should be provided for people with serious mental disorders, including for people with schizophrenia, who make high use of inpatient services and who have a history of poor engagement with services leading to frequent relapse and/or social breakdown (as manifest by homelessness or seriously inadequate accommodation). Ⓑ
- Assertive outreach teams should be provided for people with schizophrenia who are homeless. Ⓑ

- Where the needs of the service user and/or carer exceed the capacity of assertive outreach teams, referral to crisis resolution and home treatment teams, acute day hospitals or inpatient services should be considered. GPP
- Crisis resolution and home treatment teams should be considered for people with schizophrenia who are in crisis to augment the services provided by early intervention services and assertive outreach teams. Ⓒ
- Integrating the care of people with schizophrenia who receive services from community mental health teams, assertive outreach teams, early intervention services and crisis resolution and home treatment teams should be carefully considered. The CPA should be the main mechanism by which the care of individuals across services is properly managed and integrated. GPP

Psychological interventions

Psychological treatments should be an indispensable part of the treatment options available for service users and their families in the effort to promote recovery. Those with the best evidence of effectiveness are cognitive behavioural therapy and family interventions. These should be used to prevent relapse, to reduce symptoms, increase insight and promote adherence to medication. Relapse prevention and symptom reduction: cognitive behavioural therapy and family interventions

- Cognitive behavioural therapy should be available as a treatment option for people with schizophrenia. Ⓐ
- In particular, cognitive behavioural therapy should be offered to people with schizophrenia who are experiencing persisting psychotic symptoms. Ⓐ
- Cognitive behavioural therapy should be considered as a treatment option to assist in the development of insight. Ⓑ
- Cognitive behavioural therapy may be considered as a treatment option in the management of poor treatment adherence. Ⓒ
- Longer treatments with cognitive behavioural therapy are significantly more effective than shorter ones, which may improve depressive symptoms but are unlikely to improve psychotic symptoms. An adequate course of cognitive

behavioural therapy to generate improvements in psychotic symptoms in these circumstances should be of more than 6 months' duration and include more than ten planned sessions. Ⓑ

- Family interventions should be available to the families of people with schizophrenia who are living with or who are in close contact with the service user. Ⓐ
- In particular, family interventions should be offered to the families of people with schizophrenia who have recently relapsed or who are considered at risk of relapse. Ⓐ
- Also in particular, family interventions should be offered to the families of people with schizophrenia who have persisting symptoms. Ⓐ
- When providing family interventions, the length of the family intervention programme should normally be longer than 6 months' duration and include more than ten sessions of treatment. Ⓑ
- When providing family interventions, the service user should normally be included in the sessions, as doing so significantly improves the outcome. Sometimes, however, this is not practicable. Ⓑ
- When providing family interventions, service users and their carers may prefer single-family interventions rather than multi-family group interventions. Ⓐ

Pharmacological interventions

Antipsychotic drugs are an indispensable treatment option for most people in the recovery phase of schizophrenia. The main aim here is to prevent relapse and help keep a person stable enough to live as normal a life as possible. Drugs are also necessary for psychological treatments to be effective.

The service user and clinician should jointly decide the choice of drug, but service user preferences are central. Oral and depo preparations can be used. Follow BNF guidance on dosing and test dosing. If conventional antipsychotics have been used and are not effective or are causing unacceptable side effects, change to an atypical. If an atypical is causing diabetes or excessive weight gain, this must be monitored or consider changing to a different atypical or a conventional antipsychotic. Always monitor and record clinical response, side effects and service user satisfaction. If a person is satisfied with the drug he or she is taking, make no changes. Do consider the use of psychological interventions if a person has persisting symptoms or frequent relapses.

If a service user has had two antipsychotics (including one atypical) each for 6–8 weeks without significant improvement, check out possible causes for a lack of response and consider clozapine. In some circumstances it may be supportable to add a second antipsychotic drug to clozapine if there has been a suboptimal response at standard doses. Do not use more than one antipsychotic drug in other situations, except when changing from one drug to another. Other adjunctive treatments are outside the scope of this guideline. Relapse prevention: oral antipsychotics

RELAPSE PREVENTION: ORAL ANTIPSYCHOTICS

- The choice of antipsychotic drug should be made jointly by the individual and the clinician responsible for treatment based on an informed discussion of the relative benefits of the drugs and their side-effect profiles. The individual's advocate or carer should be consulted where appropriate. NICE 2002
- The oral atypical antipsychotic drugs (amisulpride, olanzapine, quetiapine, risperidone and zotepine) should be considered as treatment options for individuals currently receiving typical antipsychotic drugs who, despite adequate symptom control, are experiencing unacceptable side effects, and for those in relapse who have previously experienced unsatisfactory management or unacceptable side effects with typical antipsychotic drugs. The decision as to what are unacceptable side effects should be taken following discussion between the patient and the clinician responsible for treatment. NICE 2002
- It is not recommended that, in routine clinical practice, individuals change to one of the oral atypical antipsychotic drugs if they are currently achieving good control of their condition without unacceptable side effects with typical antipsychotic drugs. NICE 2002

- Antipsychotic therapy should be initiated as part of a comprehensive package of care that addresses the individual's clinical, emotional and social needs. The clinician responsible for treatment and key worker should monitor both therapeutic progress and tolerability of the drug on an ongoing basis. Monitoring is particularly important when individuals have just changed from one antipsychotic to another. NICE 2002
- Targeted, intermittent dosage maintenance strategies should not be used routinely in lieu of continuous dosage regimens because of the increased risk of symptom worsening or relapse. However, these strategies may be considered for service users who refuse maintenance or for whom some other contraindication to maintenance therapy exists, such as side-effect sensitivity. Ⓒ
- Antipsychotic drugs, atypical or conventional, should not be prescribed concurrently, except for short periods to cover changeover. Ⓒ

RELAPSE PREVENTION: DEPOT ANTIPSYCHOTICS

- A risk assessment should be performed by the clinician responsible for treatment and the multidisciplinary team regarding concordance with medication, and depot preparations should be prescribed when appropriate. NICE 2002
- Depot preparations should be a treatment option where a service user expresses a preference for such treatment because of its convenience, or as part of a treatment plan in which the avoidance of covert non-adherence with antipsychotic drugs is a clinical priority. Ⓑ
- For optimum effectiveness in preventing relapse, depot preparations should be prescribed within the standard recommended dosage and interval range. Ⓐ
- Following full discussion between the responsible clinician and the service user, the decision to initiate depot antipsychotic injections should take into account the preferences and attitudes of the service user towards the mode of administration and organisational procedures (for example, home visits and location of clinics) related to the delivery of regular intramuscular injections. GPP

- Test doses should normally be used as set out in the *BNF* and full licensed prescribing information on depot antipsychotics is available from the Summary of Product Characteristics, which can be found in the electronic medicines compendium (www.emc.vhn.net). GPP
- As with oral antipsychotics, people receiving depots should be maintained under regular clinical review, particularly in relation to the risks and benefits of the drug regimen. GPP

TREATMENT-RESISTANT SCHIZOPHRENIA

- The first step in the clinical management of treatment resistant schizophrenia (TRS) is to establish that antipsychotic drugs have been adequately tried in terms of dosage, duration and adherence. Other causes of non-response should be considered in the clinical assessment, such as co-morbid substance misuse, poor treatment adherence, the concurrent use of other prescribed medicines and physical illness. GPP
- If the symptoms of schizophrenia are unresponsive to conventional antipsychotics, the prescribing clinician and service user may wish to consider an atypical antipsychotic in advance of a diagnosis of treatment-resistant schizophrenia and a trial of clozapine. In such cases, olanzapine or risperidone may be worth considering. Service users should be informed that while these drugs may possibly be beneficial, the evidence for improvement in this situation is more limited than for clozapine. Ⓒ
- In individuals with evidence of TRS, clozapine should be introduced at the earliest opportunity. TRS is suggested by a lack of satisfactory clinical improvement despite the sequential use of the recommended doses for 6 to 8 weeks of at least two antipsychotics, at least one of which should be an atypical. NICE 2002

COMBINING ANTIPSYCHOTICS

- Antipsychotic drugs, atypical or conventional, should not be prescribed concurrently, except for short periods to cover changeover. Ⓒ
- However, the addition of a second antipsychotic to clozapine

may be considered for people with TRS for whom clozapine alone has proved insufficiently effective. C

Employment

The overall aim of mental health services is to help service users get back to living an ordinary life as far as possible. Assessment should be comprehensive and this includes assessing a person's work potential. Mental health and social care services also need to help support the development of employment opportunities for people with schizophrenia.

- People with schizophrenia experience considerable difficulty in obtaining employment and many remain unemployed for long periods of time. The assessment of people with schizophrenia should include assessment of their occupational status and potential. This should be recorded in their notes/care plans. GPP
- Supported employment programmes should be provided for those people with schizophrenia who wish to return to work or gain employment. However, it should not be the only work-related activity offered when individuals are unable to work or are unsuccessful in their attempts to find employment. C
- Mental health services, in partnership with social care providers and other local stakeholders, should enable people to use local employment opportunities, including a range of employment schemes to suit the different needs and level of skill, for people with severe mental health problems, including people with schizophrenia. GPP

RAPID TRANQUILLISATION

During an acute illness, some service users can become behaviourally disturbed and may need help to calm down; for the majority of service users, though, rapid tranquillisation is not necessary and should not be resorted to routinely. It is important to ensure that the environment is properly adapted for the needs of the acutely ill and that communication between staff and service users is clear and therapeutic in order to minimise frustration and misunderstandings. Staff on psychiatric inpatient units should be trained in how to assess and manage potential and actual violence using de-escalation techniques, restraint, seclusion and rapid tranquillisation. Staff should also be trained to undertake cardiopulmonary resuscitation. If drugs are needed to calm an individual, an oral preparation should be offered first. If intramuscular injection proves necessary, lorazepam, haloperidol or olanzapine are the preferred drugs. If two drugs are needed, consider lorazepam and haloperidol. If haloperidol is used, anticholinergics should be administered. Vital signs and side effects should be regularly monitored and full physical and mental health assessment undertaken at the earliest opportunity. Rapid tranquillisation may be traumatic – patients will need debriefing with full explanation, discussion and support.

- Health professionals should identify and take steps to minimise the environmental and social factors that might increase the likelihood of violence and aggression during an episode, particularly during periods of hospitalisation. Factors to be routinely identified, monitored and corrected include: overcrowding; lack of privacy; lack of activities; long waiting times to see staff; poor communication between patients and staff; and weak clinical leadership. Ⓒ

Aims of rapid tranquillisation

The aim of drug treatment in such circumstances is to calm the person, and reduce the risk of violence and harm, rather than treat the underlying psychiatric condition. An optimal response would be a reduction in agitation or aggression without sedation, allowing the service user to participate in further assessment and treatment. Ideally, the drug should have a rapid onset of action and a low level of side effects.

- Staff who use rapid tranquillisation should be trained in the assessment and management of service users specifically in this context: this should include assessing and managing the risks of drugs (benzodiazepines and antipsychotics), using and maintaining the techniques and equipment needed for cardiopulmonary resuscitation, prescribing within therapeutic limits and using flumazenil (benzodiazepine antagonist). Ⓒ

Training for behavioural control/rapid tranquillisation

- Staff need to be trained to anticipate possible violence and to de-escalate the situation at the earliest opportunity, and physical means of restraint or seclusion should be resorted to 'only after the failure of attempts to promote full participation in self-care'. Ⓒ

- Training in the use and the dangers of rapid tranquillisation is as essential as training in de-escalation and restraint. Health professionals should be as familiar with the properties of benzodiazepines as they are with those of antipsychotics. Ⓒ
- Specifically, health professionals should:
  - be able to assess the risks associated with rapid tranquillisation, particularly when the service user is highly aroused and may have been misusing drugs or alcohol, be dehydrated or possibly be physically ill
  - understand the cardio-respiratory effects of the acute administration of these drugs and the need to titrate dosage to effect
  - recognise the importance of nursing, in the recovery position, people who have received these drugs and also of monitoring pulse, blood pressure and respiration
  - be familiar with, and trained in, the use of resuscitation equipment; this is essential as an anaesthetist or experienced 'crash team' may not be available
  - undertake annual retraining in resuscitation techniques
  - understand the importance of maintaining an unobstructed airway. Ⓒ

Principles of rapid tranquillisation

- The psychiatrist and the multidisciplinary team should, at the earliest opportunity, undertake a full assessment, including consideration of the medical and psychiatric differential diagnoses. Ⓒ
- Drugs for rapid tranquillisation, particularly in the context of restraint, should be used with caution because of the following risks:
  - loss of consciousness instead of sedation
  - over-sedation with loss of alertness

  - possible damage to the therapeutic partnership between service user and clinician
  - specific issues in relation to diagnosis. C
- Resuscitation equipment and drugs, including flumazenil, must be available and easily accessible where rapid tranquillisation is used. C
- Because of the serious risk to life, service users who are heavily sedated or using illicit drugs or alcohol should not be secluded. C
- If a service user is secluded, the potential complications of rapid tranquillisation should be taken particularly seriously. C
- Violent behaviour can be managed without the prescription of unusually high doses or 'drug cocktails'. The minimum effective dose should be used. The *BNF* recommendations for the maximum doses should be adhered to unless exceptional circumstances arise. C
- With growing awareness that involuntary procedures produce traumatic reactions in service users, following the use of rapid tranquillisation, service users should be offered the opportunity to discuss their experiences and should be provided with a clear explanation of the decision to use urgent sedation. This should be documented in their notes. GPP
- Service users should also be given the opportunity to write their account of their experience of rapid tranquillisation in the notes. GPP

Route of drug administration

- Oral medication should be offered before parenteral medication. C
- If parenteral treatment proves necessary, the intramuscular route is preferred over the intravenous one from a safety point of view. Intravenous administration should only be used in exceptional circumstances. C
- Vital signs must be monitored after parenteral treatment is administered. Blood pressure, pulse, temperature and respiratory rate should be recorded at regular intervals, agreed by the multidisciplinary team, until the service user

becomes active again. If the service user appears to be or is asleep, more intensive monitoring is required. Ⓒ

Pharmacological agents used in rapid tranquillisation

- The intramuscular (IM) preparations recommended for use in rapid tranquillisation are lorazepam, haloperidol and olanzapine. Wherever possible, a single agent is preferred to a combination. Ⓒ
- When rapid tranquillisation is urgently needed, a combination of IM haloperidol and IM lorazepam should be considered. Ⓒ
- IM diazepam is not recommended for the pharmacological control of behavioural disturbances in people with schizophrenia. Ⓒ
- IM chlorpromazine is not recommended for the pharmacological control of behavioural disturbances in people with schizophrenia. Ⓒ
- When using IM haloperidol (or any other IM conventional antipsychotic) as a means of behavioural control, an anticholinergic agent should be given to reduce the risk of dystonia and other extrapyramidal side effects. Ⓒ

TECHNOLOGY APPRAISAL

Electroconvulsive therapy

Issue date – April 2003 **Review date** – November 2005

It is recommended that electroconvulsive therapy (ECT) is used only to achieve rapid and short-term improvement of severe symptoms after an adequate trial of other treatment options has proven ineffective and/or when the condition is considered to be potentially life-threatening, in individuals with:

- severe depressive illness
- catatonia
- a prolonged or severe manic episode.

The decision as to whether ECT is clinically indicated should be based on a documented assessment of the risks and potential benefits to the individual, including: the risks associated with the anaesthetic; current co-morbidities; anticipated adverse events, particularly cognitive impairment; and the risks of not having treatment.

The risks associated with ECT may be enhanced during pregnancy, in older people, and in children and young people, and therefore clinicians should exercise particular caution when considering ECT treatment in these groups.

Valid consent should be obtained in all cases where the individual has the ability to grant or refuse consent. The decision to use ECT should be made jointly by the individual and the clinician(s) responsible for treatment, on the basis of an informed discussion. This discussion should be enabled by the provision of full and appropriate information about the general risks associated with ECT (see below) and about the risks and potential benefits specific to that individual. Consent should be obtained without pressure or coercion, which may occur as a result of the circumstances and clinical setting, and the individual should be reminded of their right to withdraw consent at any point. There should be strict adherence to recognised guidelines about consent and the involvement of patient advocates and/or carers to facilitate informed discussion is strongly encouraged.

In all situations where informed discussion and consent is not possible advance directives should be taken fully into account and the individual's advocate and/or carer should be consulted.

Clinical status should be assessed following each ECT session and treatment should be stopped when a response has been achieved, or sooner if there is evidence of adverse effects. Cognitive function should be monitored on an ongoing basis, and at a minimum at the end of each course of treatment.

It is recommended that a repeat course of ECT should be considered under the circumstances indicated above only for individuals who have severe depressive illness, catatonia or mania and who have previously responded well to ECT. In patients who are experiencing an acute episode but have not previously responded, a repeat trial of ECT should be undertaken only after all other options have been considered and following discussion of the risks and benefits with the individual and/or where appropriate their carer/advocate.

As the longer-term benefits and risks of ECT have not been clearly established, it is not recommended as a maintenance therapy in depressive illness.

The current state of the evidence does not allow the general use of ECT in the management of schizophrenia to be recommended.

National information leaflets should be developed through consultation with appropriate professional and user organisations to enable individuals and their carers/advocates to make an informed decision regarding the appropriateness of ECT for their circumstances. The leaflets should be evidence based, include information about the risks of ECT and availability of alternative treatments, and be produced in formats and languages that make them accessible to a wide range of service users.

TECHNOLOGY APPRAISAL

Newer (atypical) antipsychotic drugs for schizophrenia

Issue date – June 2002 **Review date** – May 2005

The choice of antipsychotic drug should be made jointly by the individual and the clinician responsible for treatment based on an informed discussion of the relative benefits of the drugs and their side-effect profiles. The individual's advocate or carer should be consulted where appropriate.

It is recommended that the oral atypical antipsychotic drugs amisulpride, olanzapine, quetiapine, risperidone and zotepine are considered in the choice of first-line treatments for individuals with newly diagnosed schizophrenia.

The oral atypical antipsychotic drugs amisulpride, olanzapine, quetiapine, risperidone, sertindole and zotepine should be considered as treatment options for individuals currently receiving typical antipsychotic drugs who, despite adequate symptom control, are experiencing unacceptable side effects, and for those in relapse who have previously experienced unsatisfactory management or unacceptable side effects with typical antipsychotic drugs. The decision as to what are unacceptable side effects should be taken following discussion between the patient and the clinician responsible for treatment.

It is not recommended that, in routine clinical practice, individuals change to one of the oral atypical antipsychotic drugs if they are currently achieving good control of their condition without unacceptable side effects with typical antipsychotic drugs.

In individuals with evidence of treatment-resistant schizophrenia (TRS), clozapine should be introduced at the earliest opportunity, within its licensed indications. TRS is suggested by a lack of satisfactory clinical improvement despite the sequential use of the recommended doses for 6 to 8 weeks of at least two antipsychotics, typical or atypical.

A risk assessment should be performed by the clinician responsible for treatment and the multidisciplinary team regarding concordance with medication, and depot preparations should be prescribed when appropriate.

Where more than one atypical antipsychotic drug is considered appropriate, the drug with the lowest purchase cost (taking into account daily required dose and product price per dose) should be prescribed.

When full discussion between the clinician responsible for treatment and the individual concerned is not possible, in particular in the management of an acute schizophrenic episode, the oral atypical drugs should be considered as the treatment options of choice because of the lower potential risk of extrapyramidal symptoms (EPS). In these circumstances, the individual's carer or advocate should be consulted where possible and appropriate. Although there are limitations with advanced directives regarding the choice of treatment for individuals with schizophrenia, it is recommended that they are developed and documented in individuals' care programmes whenever possible.

Antipsychotic therapy should be initiated as part of a comprehensive package of care that addresses the individual's clinical, emotional and social needs. The clinician responsible for treatment and key worker should monitor both therapeutic progress and tolerability of the drug on an ongoing basis. Monitoring is particularly important when individuals have just changed from one antipsychotic to another.

Atypical and typical antipsychotic drugs should not be prescribed concurrently except for short periods to cover changeover of medication.

TECHNOLOGY APPRAISAL

Olanzapine and valproate semisodium in the treatment of acute mania associated with bipolar I disorder*

Issue date – September 2003 **Review date** – August 2006

*At the date of issue of this guidance, within the classes of agents referred to the Institute by the Department of Health and the Welsh Assembly Government only olanzapine and valproate semisodium held a marketing authorisation for the treatment of acute mania in bipolar I disorder.

Olanzapine and valproate semisodium, within their licensed indications, are recommended as options for control of the acute symptoms associated with the manic phase of bipolar I disorder.

Of the drugs available for the treatment of acute mania, the choice of which to prescribe should be made jointly by the individual and the clinician(s) responsible for treatment. The choice should be based on an informed discussion of the relative benefits and side-effect profiles of each drug, and should take into account the needs of the individual and the particular clinical situation.

In all situations where informed discussion is not possible advance directives should be taken fully into account and the individual's advocate and/or carer should be consulted when appropriate.

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TECHNOLOGY APPRAISAL

Autologous cartilage transplantation for full thickness cartilage defects in knee joints

Issue date – December 2000 **Review date** – November 2003

Autologous Cartilage Transplantation (ACT) is not currently recommended for routine primary treatment of articular cartilage defects of the knee joint in the NHS.

ACT should only be performed as part of a properly structured clinical trial, which, wherever possible, is randomised and adequately powered.

Exceptionally, ACT treatment may also be undertaken in centres participating in clinical trials of this procedure when other treatments for articular cartilage defects of the knee joint have already failed. Prospective follow up data from these cases should be collected within formal observational studies to audit the clinical effectiveness of ACT.

TECHNOLOGY APPRAISAL

Cyclo-oxygenase (Cox) II selective inhibitors, celecoxib, rofecoxib, meloxicam and etodolac for osteoarthritis and rheumatoid arthritis

Issue date – July 2001 **Review date** – May 2004

Cox II selective inhibitors and other non-steroidal anti-inflammatory drugs (NSAIDs) are indicated for pain and stiffness in inflammatory rheumatoid arthritis and for the short-term management of pain in osteoarthritis. All NSAIDs are associated with adverse events and should only be prescribed when there is a demonstrable clinical need and in accordance with their summary of product characteristics. Long-term use should be avoided without appropriate monitoring and re-evaluation of the clinical need.

Of particular concern is the propensity of NSAIDs, including the Cox II selective agents, to cause gastro-intestinal adverse events, which can include life threatening gastro-intestinal perforations, ulcers or bleeds. These agents should therefore only be prescribed after careful consideration of their risks and benefits, especially in patients who may be at increased risk of such adverse events.

Cox II selective inhibitors are not recommended for routine use in patients with rheumatoid arthritis (RA) or osteoarthritis (OA). They should be used in preference to standard NSAIDs, when clearly indicated as part of the management of RA or OA, only in patients who may be at 'high risk' of developing serious gastrointestinal adverse effects.

Patients at 'high risk' of developing serious gastrointestinal adverse events include those of 65 years of age and over, those using concomitant medications known to increase the likelihood of upper gastrointestinal adverse events, those with serious co-morbidity or those requiring the prolonged use of maximum recommended doses of standard NSAIDs. The risk of NSAID-induced complications is particularly increased in patients with a previous clinical history of gastroduodenal ulcer, gastrointestinal bleeding or gastroduodenal perforation. The use of even a Cox II selective agent should therefore be considered especially carefully in this situation.

In all patients with cardiovascular disease, there remains uncertainty over the use of Cox II selective inhibitors and they should not therefore be prescribed routinely in preference to standard NSAIDs where these are indicated in this group of patients. Furthermore, many patients with cardiovascular disease receive low dose aspirin and this carries an increased risk of gastro-intestinal events. In patients who are taking low dose aspirin, the benefit of using Cox II selective agents (to decrease gastrointestinal toxicity) is reduced. Prescribing Cox II selective agents preferentially over standard NSAIDs in this situation is therefore not justified on current evidence.

There is no evidence to justify the simultaneous prescription of gastro-protective agents with Cox II selective inhibitors as a means of further reducing potential gastrointestinal adverse events.

TECHNOLOGY APPRAISAL

Etanercept and infliximab for rheumatoid arthritis

Issue date – March 2002 **Review date** – April 2005

Etanercept and infliximab (infliximab only in combination with methotrexate) are recommended as options for the treatment of adults who have continuing clinically active rheumatoid arthritis that has not responded adequately to at least two disease-modifying anti-rheumatic drugs, including methotrexate (unless contraindicated).

Both etanercept and infliximab should be prescribed in accordance with relevant sections of the British Society for Rheumatology (BSR) guidelines, April 2001, which set out criteria for eligibility, definitions of failure of standard therapy, exclusion criteria and criteria for withdrawal of therapy. In particular, treatment should be withdrawn in the event of severe drug-related toxicity or because of lack of response at 3 months.

Prescription of these agents and follow-up of treatment response and adverse events should be undertaken only by a consultant rheumatologist specialising in their use. The choice of which of the two agents is used should be determined by consultation between the patient and the clinician responsible, taking into account differences in treatment schedules and patient preferences.

Maintenance therapy with these agents in those who respond to treatment initially should be at the lowest licensed dose compatible with continuing clinical response.

All clinicians prescribing etanercept or infliximab should (with the patient's consent) register the patient with the Biologics Registry established by the BSR and forward information on dosage, outcome and toxicity on a 6-monthly basis.

There is currently no evidence to support treatment beyond 4 years. A decision to continue therapy should therefore be contingent on ongoing monitoring of disease activity and clinical effectiveness in individual cases. Outcomes from the BSR Biologics Registry will help inform such decisions.

There is no evidence for the consecutive use of these agents, and therefore this is not recommended.

TECHNOLOGY APPRAISALS

Etanercept for juvenile idiopathic arthritis

Issue date – March 2002 **Review date** – January 2005

Etanercept is recommended for children aged 4 to 17 years with active polyarticular-course juvenile idiopathic arthritis whose condition has not responded adequately to, or who have proved intolerant of, methotrexate.

Etanercept should be prescribed in accordance with relevant sections of the British Paediatric Rheumatology Group (BPRG) protocol which sets out criteria for eligibility, definitions of failure of standard therapy, exclusion criteria and criteria for withdrawal of therapy. In particular, treatment should be withdrawn in the event of severe drug-related toxicity or because of lack of response at 6 months.

Initiation of etanercept therapy should only be undertaken by a consultant who regularly sees children and young people with juvenile idiopathic arthritis and who runs specialised paediatric rheumatology clinics. In addition, the prescribing centre should have a nurse specialist or an appropriately trained nurse who is able to teach children and parents injection techniques and who does this regularly. Follow up of treatment response and adverse events may be on a shared-care basis depending on local circumstances.

It is strongly recommended that all clinicians prescribing etanercept should (with the permission of the child and/or parent) register the child with the Biologics Registry established by the BPRG and forward information on dosage, outcome and toxicity on a quarterly basis.

There is currently no evidence to support treatment beyond 2 years and continuation of therapy is therefore contingent upon ongoing monitoring of disease activity and clinical effectiveness in individual cases.

Hip prostheses for primary hip replacement

Issue date – April 2000 **Review date** – April 2003

Using the most recent available evidence of clinical effectiveness, the best prostheses (using long term viability as the determinant) demonstrate a revision rate (the rate at which they need to be replaced) of 10% or less at 10 years. This should be regarded as the current 'benchmark' in the selection of prostheses for primary total hip replacement (THR).

The evidence used in support of any prosthesis, to establish whether or not it achieves this benchmark, should relate to data on 10 or more years follow up from a number of centres, obtained via adequately sized, well conducted observational studies (preferably with consecutive patients from non-selected populations) or randomised controlled trials. Such evidence should have been published or be available for peer review.

The Institute also considers it reasonable to recommend consideration of prostheses with a minimum of 3 years revision rate experience (collected as described above) if their performance is consistent with the benchmark of a 10% revision rate at 10 years. Prostheses that achieve this 'entry benchmark' would then need to be subject to annual review (up to 10 years) to ensure that the revision rate remains consistent with the 10 year benchmark.

Prostheses (cemented, uncemented, and hybrid) that have not been shown to achieve either of these benchmarks, should be the subject of comparative clinical evaluation before they can be recommended for routine use in the NHS.

There is currently more evidence of the long term viability of cemented prostheses, which, in many cases, occupy the lower end of the range of prostheses cost, than there is for uncemented and hybrid prosthesis.
NHS net users access hip database – nww.pasa.nhs.uk/nice

TECHNOLOGY APPRAISAL

Metal on metal hip resurfacing arthroplasty

Issue date – June 2002 **Review date** – February 2005

Metal on metal (MoM) hip resurfacing arthroplasty is recommended as one option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement. In considering hip resurfacing arthroplasty, it is recommended that surgeons take into account activity levels of potential recipients and bear in mind that the current evidence for the clinical and cost effectiveness of MoM hip resurfacing arthroplasty is principally in individuals less than 65 years of age.

When MoM hip resurfacing arthroplasty is considered appropriate, the procedure should be performed only in the context of the ongoing collection of data on both the clinical effectiveness and cost effectiveness of this technology. Ideally, this data collection should form part of a UK national joint registry.

This guidance should be read in conjunction with the Institute's guidance on devices for total hip replacement (Guidance on the selection of prostheses for primary total hip replacement: *NICE Technology Appraisal Guidance No 2*. April 2000 also in this section). In that guidance, the Institute recommended that the best prostheses (using long-term viability as the determinant) should demonstrate a 'benchmark' revision rate (the rate at which they need to be replaced) of 10% or less at 10 years or, as a minimum, a 3 year revision rate consistent with this 10-year benchmark. Establishing and confirming similar benchmarking criteria will be necessary for MoM hip resurfacing arthroplasty and will be facilitated by a UK national joint registry. In the interim, the 3 year minimum benchmark should apply to MoM hip resurfacing devices.

MoM hip resurfacing arthroplasty should be performed only by surgeons who have received training specifically in this technique.

Surgeons should ensure that patients considering MoM hip resurfacing arthroplasty understand that less is known about the medium- to long-term safety and reliability of these devices or the likely outcome of revision surgery than for conventional total hip replacements. This additional uncertainty should be weighed against the potential benefits claimed for MoM devices.

INTERVENTIONAL PROCEDURE

Minimally invasive placement of pectus bar

Issue date – July 2003

This procedure is also known as the Nuss procedure

The evidence of the safety and efficacy of minimally invasive placement of pectus bar reviewed by the Interventional Procedures Advisory Committee was not adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians should ensure that the uncertainty about the procedure's safety and efficacy is understood by the parent or carer and where possible the child, and involve the child appropriately in arrangements for informed consent. The clinician should provide them with clear written information. Use of the information for the public, produced by NICE, is recommended. Clinicians should inform the clinical governance leads in their Trusts and ensure that appropriate arrangements are in place for clinical audit or research.

All those who have the procedure should be entered, subject to their consent, onto the Registry maintained at the Wessex Regional Centre for Paediatric Surgery, Southampton General Hospital. The Registry's Surgical Co- Directors are Mr Robert Wheeler and Mr David Weeden.

It is recommended that minimally invasive placement of pectus bar be referred to the Institute's Review Body, which should liaise with the Registry and prepare an analysis of its results for the Committee to consider. Further guidance will then be issued by the Institute.

Percutaneous vertebroplasty

Issue date – September 2003

Current evidence on the safety and efficacy of percutaneous vertebroplasty appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.

The following are recommended.

- This procedure should only be undertaken when there are arrangements for good access to a spinal surgery service, and with prior discussion between a specialist multidisciplinary team that includes a radiologist and a spinal surgeon.
- Clinicians should receive training to reach an appropriate level of expertise before carrying out this procedure. In particular, they must follow the manufacturer's instructions for making the cement, to reduce the risk of embolisation.
- The procedure should be limited to patients whose pain is refractory to more conservative treatment.

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TECHNOLOGY APPRAISAL

Orlistat for the treatment of obesity in adults

Issue date – March 2001 **Review date** – February 2004

Orlistat should only be prescribed for people who have lost at least 2.5 kg in weight by dietary control and increased physical activity alone in the month prior to the first prescription and meet one of the following criteria:

- a body mass index (BMI) of 28 kg/m^2 or more in the presence of significant co-morbidities which persist despite standard treatment, (e.g. type 2 diabetes, high blood pressure and/or high total cholesterol level).
- a BMI of 30 kg/m^2 or more with no associated co-morbidities.

Orlistat should only be prescribed for people between the ages of 18 and 75 years.

When treatment with orlistat is offered, arrangements should be made for appropriate health professionals to offer specific concomitant advice, support and counselling on diet, physical activity and behavioural strategies.

Continuation of this therapy beyond three months should be supported by evidence of a loss of at least a further 5% of body weight from the start of drug treatment.

Continuation of this therapy beyond six months should be supported by evidence of a cumulative weight loss of at least 10% of body weight from the start of drug treatment.

Treatment should not usually be continued beyond 12 months, and never beyond 24 months.

TECHNOLOGY APPRAISAL

Sibutramine for obesity in adults

Issue date – October 2001 **Review date** – September 2004

Sibutramine should be prescribed only as part of an overall treatment plan for management of nutritional obesity in people aged 18–65 years who meet one of the following criteria:

- a body mass index (BMI) of 27.0 kg/m^2 or more in the presence of significant co-morbidities
- a BMI of 30.0 kg/m^2 or more without associated co-morbidities.

Sibutramine should be prescribed, in accordance with the Summary of Product Characteristics, only for people who have made previous serious attempts to lose weight by diet, exercise and/or other behavioural modifications.

When treatment with sibutramine is offered, arrangements should be made for appropriate health professionals to offer specific concomitant advice, support and counselling on diet, physical activity and behavioural strategies. Sibutramine should not be prescribed unless adequate arrangements for monitoring both weight loss and adverse effects can be made available.

The starting dose of sibutramine should normally be 10 mg/day. Continuation of this therapy beyond 4 weeks should be supported by evidence of a 2 kg weight loss, and beyond 3 months should be supported by evidence of a loss of at least 5% of initial body weight from the start of drug treatment. Dosage may be increased to 15 mg/day after 4 weeks in line with sibutramine's Summary of Product Characteristics, and the same treatment and monitoring regimens followed as for the 10 mg/day dose. Sibutramine therapy should be stopped if there is inadequate response, as defined above.

Since the use of sibutramine may increase blood pressure of some individuals, blood pressure must be checked regularly in all those to whom it is prescribed. If blood pressure increases, continuation of sibutramine therapy must be reconsidered taking into account the risks and benefits of the effects of treatment on cardiovascular risk profile for the individual. Treatment with sibutramine is not recommended for individuals whose blood pressure before start of therapy is above 145/90 mmHg. Treatment should be discontinued in people whose blood pressure rises above 145/90 mmHg or by more than 10 mmHg (systolic or diastolic) or whose resting pulse rate rises by more than 10 beats per minute.

Treatment is not recommended beyond the licensed indication of 12 months.

There is no evidence to support the co-prescribing of sibutramine with other pharmacotherapy aimed at weight reduction.

TECHNOLOGY APPRAISAL

Surgery to aid weight reduction for people with morbid obesity

Issue date – July 2002 **Review date** – June 2005

For the purposes of this guidance, people are defined as having morbid obesity if they have a body mass index (BMI) either equal to or greater than 40 kg/m^2, or between 35 kg/m^2 and 40 kg/m^2 in the presence of significant co-morbid conditions that could be improved by weight loss.

People with morbid obesity who are considering surgery to aid weight reduction should discuss in detail with the clinician responsible for their treatment (that is, the hospital specialist and/or bariatric surgeon) the potential benefits and longer-term implications of surgery, as well as the associated risks, including complications and postoperative mortality.

Surgery is recommended as a treatment option for people with morbid obesity providing all of the following criteria are fulfilled:

- this type of surgery should be considered only for people who have been receiving intensive management in a specialised hospital obesity clinic
- individuals should be aged 18 years or over
- there should be evidence that all appropriate and available non-surgical measures have been adequately tried but have failed to maintain weight loss
- there should be no specific clinical or psychological contra-indications to this type of surgery
- individuals should be generally fit for anaesthesia and surgery

- individuals should understand the need for long-term follow-up.

Surgery should be undertaken only after comprehensive, multidisciplinary assessment. In addition, arrangements should be made for appropriate healthcare professionals to provide pre-operative and postoperative counselling and support to individuals being considered for surgery.

Given the uncertainty surrounding the evidence for the relative safety and effectiveness of different surgical interventions, it is not possible to distinguish between them on grounds of cost effectiveness. The choice of surgical intervention should therefore be made jointly by the individual and the clinician after considering the best available evidence, the facilities and equipment available, and the experience of the surgeon who would perform the operation.

Databases should be established by hospitals wanting to develop their service, to enable the outcomes and complications of different procedures, including their impact on quality of life, to be monitored both in the short and long term.

It is important that services and skills to support surgery for people with morbid obesity are developed in a planned and coordinated way. Existing collective mechanisms for specialist commissioning groups may offer an appropriate way for the development of detailed implementation strategies. Each group, in discussion with other groups, should decide how best to develop and expand the service, and the number of sites from which it should be provided.

Renal and urinary

Interventional Procedure

Sacral nerve stimulation for urge incontinence 267 NEW

Transurethral electrovapourisation of prostate (TEVAP) 268 NEW

Transurethral radiofrequency needle ablation of prostate (TUNA) 268 NEW

Technology Appraisals

Home compared with hospital haemodialysis for patients with end-stage renal failure 266

TECHNOLOGY APPRAISAL

Home compared with hospital haemodialysis for patients with end-stage renal failure

Issue date – September 2002 **Review date** – August 2005

NOTE

This provides guidance on the location in which haemodialysis is carried out; it does not address the wider issues of frequency of dialysis sessions and how haemodialysis compares with other forms of renal replacement therapy. These recommendations are applicable only to those patients who, after detailed assessment of all their treatment options, have been defined as being suitable for haemodialysis.

It is recommended that all suitable patients should be offered the choice between home haemodialysis or haemodialysis in a hospital/satellite unit.

In general, patients suitable for home haemodialysis will be those who:

- have the ability and motivation to learn to carry out the process and the commitment to maintain treatment
- are stable on dialysis
- are free of complications and significant concomitant disease that would render home haemodialysis unsuitable or unsafe
- have good functioning vascular access
- have a carer who has (or carers who have) also made an informed decision to assist with the haemodialysis unless the individual is able to manage on his or her own
- have suitable space and facilities or an area that could be adapted within their home environment.

A full assessment of the patient's clinical needs, social circumstances and home environment is necessary to determine his or her suitability for home haemodialysis. In order to make an informed choice about the location of haemodialysis that is most suitable for their particular circumstances, patients and all potential carers should be fully informed regarding what is involved in the different options, and the potential impact on their lives and those of their households should be discussed. All potential carer(s) should be given the opportunity to express their views independently of the patient. An opportunity to review the decision to proceed or continue with home haemodialysis should be available in the event of any change in circumstances.

Patients currently treated in hospital who are potentially suitable for home haemodialysis on clinical grounds, but who have not previously been offered a choice, should be reassessed and informed about their dialysis options.

Patients performing haemodialysis at home and their carers will require initial training and an accessible and responsive support service. The support service should offer the possibility of respite hospital/satellite unit dialysis as required.

INTERVENTIONAL PROCEDURE

Sacral nerve stimulation for urge incontinence

Issue date – August 2003

Current evidence of the safety and efficacy of sacral nerve stimulation for urge incontinence does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake sacral nerve stimulation for urge incontinence should inform the clinical governance leads in their trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty.

Patients should be selected on the basis of their response to peripheral nerve evaluation.

NICE has commissioned a systematic review of sacral nerve stimulation for urge incontinence, together with sacral nerve stimulation for faecal incontinence.

INTERVENTIONAL PROCEDURE

Transurethral electrovapourisation of prostate (TEVAP)

Current evidence on the safety and efficacy of transurethral electrovaporisation of the prostate (TEVAP) appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.

INTERVENTIONAL PROCEDURE

Transurethral radiofrequency needle ablation of prostate (TUNA)

Current evidence on the safety and short-term efficacy of transurethral radiofrequency needle ablation of the prostate appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.

Respiratory

Technology Appraisals

Inhaler devices for chronic asthma in older children (aged 5–15) 270

Inhaler systems for under–5s 271

TECHNOLOGY [illegible]

Inhaler devices for chronic asthma in older children (aged 5–15)

Issue date – March 2002 **Review date** – April 2005

It is recommended that in addition to therapeutic need (including chosen drug and dose), the following factors be taken into account when choosing inhaler devices for individual children with chronic asthma:

- the ability of the child to develop and maintain an effective technique with the specific device
- the suitability of a device for the child's and carer's lifestyles, considering factors such as portability and convenience
- the child's preference for and willingness to use a particular device.

The general recommendations in the above should be taken into account when considering the following specific guidance:

- A press-and-breathe pressurised metered dose inhaler (pMDI) and suitable spacer device is recommended as the first-line choice for the delivery of inhaled corticosteroids as part of regular planned daily therapy, with the aim of maximising benefits of preventive therapy in attaining good asthma control, and minimising potential systemic absorption. Where clinicians believe that an individual child's adherence to the press-and-breathe pMDI and spacer combination is likely to be so poor as to undermine effective asthma control, other alternative devices (taking account of the factors outlined above and evidence of equivalence of clinical effectiveness) should be considered, bearing in mind the need to minimise the risks of systemic absorption of corticosteroids.
- In the case of other inhaled drugs, primarily bronchodilators, it is recommended that a wider range of devices be considered to take account of their more frequent spontaneous use, the greater need for portability, and the clear feedback that symptom response provides to the device user. In such circumstances the factors outlined above are likely to be of greater importance in choosing a device.

Where more than one device satisfies the considerations outlined above in a particular child, it is recommended that the device with the lowest overall cost (taking into account daily required dose and product price per dose) should be chosen.

On selection of an inhaler device, it is important that consideration is given to other aspects of asthma care that influence the effective delivery of inhaled therapy, including:

- individual practical training in the use of the specific device
- monitoring of effective inhaler technique and adherence to therapy
- regular (i.e. no less than annual) review of inhaler needs, which may change over time with increasing age.

TECHNOLOGY APPRAISAL

Inhaler systems for under–5s

Issue date – August 2000 **Review date** – August 2003

For children under the age of 5 years with chronic stable asthma both corticosteroids and bronchodilator therapy should be routinely delivered by pressurised metered dose inhaler (pMDI) and spacer system, with a face mask where necessary.

Where this combination is not clinically effective for the child and depending on the child's condition, nebulised therapy may be considered. In the case of children aged 3 to 5 years, a dry powder inhaler (DPI) may also be considered.

Choice of device to be made within the pMDI and spacer range should be primarily governed by specific individual need and the likelihood of good compliance. Once these factors have been taken into account, choice should be made on the basis of cost minimisation.

Skin disorders and wounds

Clinical Guideline

Pressure ulcer prevention — Pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care 274 NEW

Technology Appraisals

Debriding agents and specialist wound care clinics for difficult to heal surgical wounds 273

TECHNOLOGY APPRAISAL

Debriding agents and specialist wound care clinics for difficult to heal surgical wounds

Issue date – April 2001 **Review date** – March 2004

There is no RCT evidence to support any particular method of debridement for difficult to heal surgical wounds, but less robust studies suggest modern dressings (products thought to promote autolytic wound debridement, including hydrocolloids, hydrogels, polysaccharide beads/paste, foam dressings, and alginate dressings) as well as bio-surgical techniques (sterile maggots) may reduce pain and be more acceptable to patients.

In the absence of sufficient evidence for or against any particular method of debridement, or for one type of modern dressing over another, the choice of debriding agent for difficult to heal surgical wounds should be based on impact on comfort, odour control and other aspects relevant to patient acceptability; type and location of wound; and total costs. Costs of wound care are very sensitive to the frequency with which dressings are changed; this applies particularly to home wound care requiring a visit by a nurse.

Although there is no direct evidence to support the provision of specialist wound care services for managing difficult to heal surgical wounds, a structured approach to care (including pre-operative assessments to identify individuals with potential wound healing problems) is required in order to improve overall management of surgical wounds. To support this, enhanced education of health care workers, patients and carers, and sharing of clinical expertise will be required.

CLINICAL GUIDELINE

Pressure ulcer prevention – Pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care*

Issue date – October 2003 **Review date** – October 2007

* Incorporates the recommendations of the inherited Clinical Guideline *Pressure Ulcer Risk Management and Prevention*, published in April 2001.

The recommendations in this document are derived from two clinical guidelines, *Pressure ulcer risk assessment and prevention* and *Clinical practice guideline for pressure-relieving devices: the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care*, which use different grading schemes. The grading schemes are described below. Summaries of the evidence on which the guidance is based are provided in the full guidelines, available from www.nice.org.uk. The guideline on pressure ulcer risk assessment and prevention was published in 2001. Its recommendations have been incorporated into this document, but the evidence used to develop it was not reviewed or updated during the development of the guideline on pressure-relieving devices.

The grading scheme and hierarchy of evidence used in *Clinical practice guideline for pressure-relieving devices: the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care* (see Table) is from Eccles and Mason (2001).

Recommendation Grade	Evidence
Ⓐ	directly based on category I evidence
Ⓑ	directly based on • category II evidence, or • extrapolated recommendation from category I evidence

Recommendation Grade	**Evidence**
Ⓒ	directly based on • category III evidence, or • extrapolated recommendation from category I or II evidence
Ⓓ	directly based on • category IV evidence, or • extrapolated recommendation from categoryI, II or III evidence

Evidence category	**Source**
I	Evidence from: • meta-analysis of randomised controlled trials, **or** • at least one randomised controlled trial
II	Evidence from: • at least one controlled study without randomisation, **or** • at least one other type of quasi-experimental study
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case–control studies
IV	Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

Adapted from Eccles M, Mason J (2001) How to develop costconscious guidelines. *Health Technology Assessment* 5: 16

The grading scheme used in *Pressure ulcer risk assessment and prevention* was adapted from Waddell G., Feder G., McIntosh A., Lewis M. et al. (1996) *Low back pain evidence review*. London: Royal College of General Practitioners)

EVIDENCE

1 Generally consistent finding in a majority of multiple acceptable studies

2 Either based on a single acceptable study, or a weak or inconsistent finding in multiple acceptable studies

3 Limited scientific evidence which does not meet all the criteria of acceptable studies or absence of directly applicable studies of good quality. This includes expert opinion.

('Acceptable' for this guideline refers to those that have been subjected and approved by a process of critical appraisal. For further details see: Rycroft-Malone J, McInnes E (2001) *Pressure ulcer risk assessment and prevention guideline: Technical Report*. London: Royal College of Nursing. Available from www.rcn.org.uk).

The recommendations in this guidance are of relevance to:

- those who are vulnerable to or at elevated risk of developing pressure ulcers
- families and carers
- healthcare professionals who share in caring for those who are vulnerable to or at elevated risk of developing pressure ulcers
- those with responsibility for purchasing pressure-relieving devices.

RISK ASSESSMENT AND PREVENTION

Identifying individuals vulnerable to or at elevated risk of pressure ulcers

- Assessing an individual's risk of developing pressure ulcers should involve both informal and formal assessment procedures.③
- Risk assessment should be carried out by personnel who have undergone appropriate training to recognise the risk factors that contribute to the development of pressure ulcers and know how to initiate and maintain correct and suitable preventative measures.③
- The timing of risk assessment should be based on each individual case. However, it should take place within 6 hours of the start of admission to the episode of care.③
- If an individual is considered **not** to be vulnerable to or at elevated risk of pressure ulcers on initial assessment,

reassessment should occur if there is a change in an individual's condition that increases risk (see bullet above).❸

- All formal assessments of risk should be documented/recorded and made accessible to all members of the interdisciplinary team.❸

Use of risk assessment tools

- Risk assessment tools should only be used as an aide memoire and should not replace clinical judgment.❶

Risk factors

- An individual's potential to develop pressure ulcers may be influenced by the following intrinsic risk factors, which therefore should be considered when performing a risk assessment:
  - reduced mobility or immobility
  - sensory impairment
  - acute illness
  - level of consciousness
  - extremes of age;
  - vascular disease
  - severe chronic or terminal illness
  - previous history of pressure damage
  - malnutrition and dehydration.❷
- The following extrinsic risk factors are involved in tissue damage and should be removed or diminished to prevent injury: pressure, shearing and friction.❷
- The potential of an individual to develop pressure ulcers may be exacerbated by the following factors, which therefore should be considered when performing a risk assessment: medication and moisture to the skin.❷

Skin inspection

- Skin inspection should occur regularly and the frequency determined in response to changes in the individual's condition in relation to either deterioration or recovery.❸

- Skin inspection should be based on an assessment of the most vulnerable areas of risk for each patient. These are typically: heels; sacrum; ischial tuberosities; parts of the body affected by anti-embolic stockings; femoral trochanters; parts of the body where pressure, friction or shear is exerted in the course of an individual's daily living activities; parts of the body where there are external forces exerted by equipment and/or clothing; elbows; temporal region of skull; shoulders; back of head and toes.❸ Other areas should be inspected as necessitated by the patient's condition.
- Individuals who are willing and able should be encouraged, following education, to inspect their own skin.❸
- Individuals who are wheelchair users should use a mirror to inspect the areas that they cannot see easily or get others to inspect them.❸
- Healthcare professionals should be aware of the following signs, which may indicate incipient pressure ulcer development: persistent erythema; non-blanching hyperaemia previously identified as non-blanching erythema; blisters; discolouration; localised heat; localised oedema and localised induration. In those with darkly pigmented skin: purplish/bluish localised areas of skin; localised heat that, if tissue becomes damaged, is replaced by coolness; localised oedema and localised induration.❸
- Skin changes should be documented/recorded immediately.❸

PRESSURE ULCER PREVENTION

Positioning

- Individuals who are vulnerable to or at elevated risk of pressure ulcer development should be repositioned and the frequency of repositioning determined by the results of skin inspection and individual needs, not by a ritualistic schedule.❸
- Repositioning should take into consideration other relevant matters, including the patient's medical condition, their comfort, the overall plan of care and the support surface.❸
- Positioning of patients should ensure that: prolonged pressure on bony prominences is minimised, bony

prominences are kept from direct contact with one another, and friction and shear damage is minimised.③

- A re-positioning schedule, agreed with the individual, should be recorded and established for each person vulnerable to pressure ulcers.③
- Individuals or carers, who are willing and able, should be taught how to redistribute weight.③
- Manual handling devices should be used correctly in order to minimise shear and friction damage. After manoeuvring, slings, sleeves or other parts of the handling equipment should not be left underneath individuals.③

Seating

- Seating assessments for aids and equipment (otherwise known as assistive technologies) should be carried out by trained assessors who have the acquired specific knowledge and expertise (for example, physiotherapists or occupational therapists).③
- Advice from trained assessors with acquired specific knowledge and expertise should be sought about correct seating positions.③
- Positioning of individuals who spend substantial periods of time in a chair or wheelchair should take into account distribution of weight, postural alignment and support of feet.③
- The management of a patient in a sitting position is important. Even with appropriate pressure relief, it may be necessary to restrict sitting time to less than 2 hours until the condition of an individual with an elevated risk changes.Ⓓ
- No seat cushion has been shown to perform better than another, so this guideline makes no recommendation about which type to use for pressure redistribution purposes.③

Use of aids

- The following should not be used as pressure-relieving aids: water-filled gloves; synthetic sheepskins*; doughnut-type devices.③

  * Since the guideline on pressure ulcer prevention and assessment was published a study in Australia has

suggested that natural sheepskin may be effective in pressure ulcer prevention.

Pressure-relieving devices (beds, mattresses and overlays)

- Decisions about which pressure-relieving device to use should be based on cost considerations and an overall assessment of the individual. Holistic assessment should include all of the following:
  - identified levels of risk
  - skin assessment
  - comfort
  - general health state
  - lifestyle and abilities
  - critical care needs
  - acceptability of the proposed pressure-relieving equipment to the patient and/or carer

  and should not be based solely on scores from risk assessment tools.Ⓓ
- All individuals assessed as being vulnerable to pressure ulcers should, as a minimum provision, be placed on a high-specification foam mattress with pressure-relieving properties.Ⓑ
- Although there is no research evidence that high-tech pressure relieving mattresses and overlays are more effective than high-specification (low-tech) foam mattresses and overlays, professional consensus recommends that consideration should be given to the use of alternating pressure or other high-tech pressure-relieving systems:
  - as a first-line preventative strategy for people at elevated risk as identified by holistic assessment
  - when the individual's previous history of pressure ulcer prevention and/or clinical condition indicates that he or she is best cared for on a high-tech device
  - when a low-tech device has failed.Ⓓ
- All individuals undergoing surgery and assessed as being vulnerable to pressure ulcers should, as a minimum

provision, be placed on either a high-specification foam theatre mattress or other pressure-redistributing surface.Ⓓ

- The provision of pressure-relieving devices needs a 24-hour approach. It should include consideration of all surfaces used by the patient.Ⓓ
- Support surface and positioning needs should be assessed and reviewed regularly and determined by the results of skin inspection, and patient comfort, ability and general state. Thus repositioning should occur when individuals are on pressure-relieving devices.Ⓓ
- A pressure ulcer reduction strategy should incorporate a coordinated approach to the acquisition, allocation and management of pressure-relieving equipment. The time elapsing between assessment and use of the device should be specified in this strategy.Ⓓ

Education and training

- All healthcare professionals should receive relevant training or education in pressure ulcer risk assessment and prevention.②
- An interdisciplinary approach to the training and education of healthcare professionals should be adopted.③
- Training and education programmes for healthcare professionals should include:
  - risk factors for pressure ulcer development
  - pathophysiology of pressure ulcer development
  - the limitations and potential applications of risk assessment tools
  - skin assessment
  - skin care
  - selection of pressure relieving equipment
  - use of pressure-relieving equipment
  - maintenance of pressure relieving equipment
  - methods of documenting risk assessments and prevention activities
  - positioning to minimise pressure

  - shear and friction damage including the correct use of manual handling devices
  - roles and responsibilities of interdisciplinary team members in pressure ulcer management
  - policies and procedures regarding transferring individuals between care settings
  - providing education and information to patients.❸

- Healthcare professionals with recognised training in pressure ulcer management should cascade their knowledge and skills to their local healthcare teams.❸
- Individuals vulnerable to or at elevated risk of developing pressure ulcers who are able and willing should be informed and educated about risk assessment and resulting prevention strategies. This strategy should, where appropriate, include carers.❸
- Education for individuals vulnerable to pressure ulcers, and their carers, should include providing information verbally and in writing on the following:
  - the risk factors associated with developing pressure ulcers
  - the sites that are of the greatest risk of pressure damage
  - how to inspect skin and recognise skin changes
  - how to care for skin
  - methods for pressure relief/reduction
  - the use and maintenance of pressure-relieving devices
  - where patients/carers can seek further advice and assistance
  - the need for immediate visits to a healthcare professional if signs of damage are noticed.Ⓓ

Equipment safety

Equipment safety is an important issue in relation to the use of pressure-relieving devices. In particular, cross-infection is possible where equipment is inadequately decontaminated between patients (Orr et al. 1994) and injury is possible if users of such equipment (patients, carers and health professionals) have not been educated about appropriate use. Guideline users are therefore referred to the standards on medical devices management and decontamination of reusable medical devices (Medical Devices Agency 2002a; 2002b). Users of these guidelines are encouraged to familiarise themselves with the sections of these documents relevant to the use and decontamination of pressure-relieving devices. Anecdotal evidence suggests that if there is no access to adequate decontamination facilities it may be desirable to lease pressure-relieving devices. The advantage of leasing in these circumstances is that the devices can be returned to the manufacturer for thorough decontamination after each patient use.

Orr KE, Gould FK, Perry JS et al (1994) Therapeutic beds: the Trojan horses of the 1990s? *Lancet* 344: 65–66

Medical Devices Agency (2002a) *Medical Devices Management* London: Medical Devices Agency

Medical Devices Agency (2002b) *De-contamination of re-usable medical devices* London: Medical Devices Agency

Miscellaneous

Clinical Guideline

Preoperative tests – The use of routine preoperative tests for elective surgery 285 NEW

Technology Appraisals

Ultrasound locating devices for placing central venous catheters 301

CLINICAL GUIDELINE

Preoperative tests – The use of routine preoperative tests for elective surgery

Issue date – June 2003 **Review date** – June 2007

This guideline makes recommendations to help guide the appropriate use of routine preoperative tests for patients before elective surgery for children (ASA grade 1) and adults (ASA grades 1, 2 and 3). The guideline is aimed mainly at secondary care, but may have relevance to some tests carried out or ordered in primary care.

The following guidance is based upon the best available evidence. All of the recommendations are grade D recommendations, which are based upon level IV evidence* – that is, expert opinion derived from a consensus development process and the clinical experience of the Guideline Development Group.

* For more information, see NICE (2001). *Information for National Collaborating Centres and Guideline Development Groups*. Available from: www.nice.org.uk/Docref.asp?d=25652

The recommendations are in the form of 'look-up' tables. For the following tests the tables are set out by surgery grade (see Box 1) and ASA grade (see Boxes 2 and 3).

- Plain **chest X-ray** (radiograph)
- Resting electrocardiogram **(ECG)**
- **Full blood count**
- **Haemostasis** – including prothrombin time, activated partial thromboplastin time and international normalised ratio
- **Renal function** (including tests for potassium, sodium, creatinine and/or urea levels)
- **Random** blood **glucose**
- **Urine analysis** (urine dipstick tests – test for pH, protein, glucose, ketones, blood/haemoglobin)
- **Blood gases** – for ASA grades 2 and 3 only

- **Lung function** (peak expiratory flow rate, forced vital capacity and forced expiratory volume) – for ASA grades 2 and 3 only.

There are also recommendations for sickle cell test and pregnancy test.

The recommendations are colour-coded in a similar way to traffic lights.

● Test not recommended

◍ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

For the tables set out by surgery grade and ASA grade, age categories are shown across the top each table. For a patient with more than one comorbidity, follow the recommendations in all relevant tables.

Box 1 Surgery grades

	Example
Grade 1 (minor)	Excision of lesion of skin; drainage of breast abscess
Grade 2 (intermediate)	Primary repair of inguinal hernia; excision of varicose vein(s) of leg; tonsillectomy/ adenotonsillectomy; knee arthroscopy
Grade 3 (major)	Total abdominal hysterectomy; endoscopic resection of prostrate; lumbar discectomy; thyroidectomy
Grade 4 (major +)	Total joint replacement; lung operations; colonic resection; radical neck dissection
Neurosurgery	–
Cardiovascular surgery	–

Box 2 ASA grades

ASA (American Society of Anesthesiologists) grades are a simple scale describing fitness to undergo an anaesthetic. The ASA clearly states that it does not endorse any elaboration of these definitions. However, anaesthetists in the UK often qualify (or interpret) these grades as relating to functional capacity – that is comorbidity that does not (ASA Grade 2) or that does (ASA Grade 3) limit a patient's activity (see Box 3).

ASA Grade 1	"Normal healthy patient" (that is without any clinically important comorbidity and without clinically significant past/present medical history)
ASA Grade 2	"A patient with mild systemic disease"
ASA Grade 3	"A patient with severe systemic disease"
ASA Grade 4	"A patient with severe systemic disease that is a constant threat to life"

Box 3 Characterisation of 'mild' and 'severe' comorbidity, corresponding to ASA grades 2 and 3, for cardiovascular, respiratory and renal comorbidities

	ASA Grade 2: "A patient with mild systemic disease"	**ASA Grade 3: "A patient with severe systemic disease"**
Cardiovascular disease		
Current angina	Occasional use of GTN spray (2–3 times per month). Does not include patients with unstable angina who would be ASA 3	Regular use of GTN spray (2–3 times per week) or unstable angina
Exercise tolerance	Not limiting activity	Limiting activity
Hypertension	Well controlled using a single anti-hypertensive medication	Not well controlled, requiring multiple anti-hypertensive medications
Diabetes	Well controlled, no obvious diabetic complications	Not well controlled, diabetic complications (e.g. claudication, impaired renal function)
Previous coronary revascularisation	Not directly relevant – depends on current signs and symptoms	Not directly relevant – depends on current signs and symptoms

Box 3 Characterisation of 'mild' and 'severe' comorbidity, corresponding to ASA grades 2 and 3, for cardiovascular, respiratory and renal comorbidities (continued)

	ASA Grade 2:	ASA Grade 3:
Respiratory disease		
COAD/COPD	Productive cough; wheeze well controlled by inhalers; occasional episodes of acute chest infection	Breathlessness on minimal exertion (for example, stair climbing, carrying shopping); distressingly wheezy much of the time; several episodes per year of acute chest infection
Asthma	Well controlled by medications/inhalers; not limiting life-style	Poorly controlled; limiting life-style; on high dose of inhaler/oral steroids; frequent hospital admission on account of asthma exacerbation
Renal disease		
	Elevated creatinine (creatinine > 100 μmol/litre and < 200 μmol/litre); some dietary restrictions	Documented poor renal function (creatinine > 200 μmol/litre); regular dialysis programme, (peritoneal or haemodialysis)

COAD, chronic obstructive airways disease; COPD, chronic obstructive pulmonary disease; GTN, glyceryl trinitrate

Further examples are available in Appendix 2 of the full guideline *Preoperative tests.The use of routine preoperative tests for elective surgery. Evidence, methods and guidance*, available on the NICE website www.nice.org.uk

Grade 1 surgery (minor)

ASA Grades

Grade 1 Normal healthy patient (i.e. without any clinically important comorbidity and without a clinically significant past/present medical history).

Grade 2 Patient with mild systemic disease

Grade 3 A patient with severe systemic disease but the disease is not a constant threat to life.

See Boxes 2 and 3 for more information

● Test not recommended

◍ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

ASA Grade 1: children < 16 years

Test	Age				
	< 6 months	≥ 6 to < 12 months	≥ 1 to < 5 years	≥ 5 to < 12 years	≥ 12 to < 16 years
Chest X-ray	No	No	No	No	No
ECG	No	No	No	No	No
Full blood count	No	No	No	No	No
Haemostasis	No	No	No	No	No
Renal function	No	No	No	No	No
Random glucose	No	No	No	No	No
Urine analysis*	No	No	No	No	No

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 1: adults ≥ 16 years

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	No	No	No	No
ECG	No	▨	▨	Yes
Full blood count	No	No	▨	▨
Haemostasis	No	No	No	No
Renal function	No	No	▨	▨
Random glucose	No	No	No	No
Urine analysis*	▨	▨	▨	▨

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 2: adults with comorbidity from **cardiovascular disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	No	▨	▨	▨
ECG	Yes	Yes	Yes	Yes
Full blood count	▨	▨	▨	▨
Haemostasis	No	No	No	No
Renal function	▨	▨	▨	▨
Random glucose	No	No	No	No
Urine analysis	▨	▨	▨	▨
Blood gases	No	No	No	No
Lung function	No	No	No	No

ASA Grade 3: adults with comorbidity from **cardiovascular disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG	Yes	Yes	Yes	Yes
Full blood count	▨	▨	▨	▨
Haemostasis	No	No	No	No
Renal function	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	No	No	No	No

Grade 1 surgery (minor) continued

ASA Grades

Grade 1 Normal healthy patient (i.e. without any clinically important comorbidity and without a clinically significant past/present medical history).

Grade 2 Patient with mild systemic disease

Grade 3 A patient with severe systemic disease but the disease is not a constant threat to life.

See Boxes 2 and 3 for more information

● Test not recommended

▨ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

ASA Grade 2: adults with comorbidity from **respiratory disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	No	▨	▨	▨
ECG	No	▨	▨	▨
Full blood count	▨	▨	▨	▨
Haemostasis	No	No	No	No
Renal function	No	No	▨	▨
Random glucose	No	No	No	No
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	No	No	No	No

ASA Grade 3: adults with comorbidity from **respiratory disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG	▨	▨	▨	▨
Full blood count	▨	▨	▨	▨
Haemostasis	No	No	No	No
Renal function	▨	▨	▨	▨
Random glucose	No	No	No	No
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	No	No	No	No

ASA Grade 2: adults with comorbidity from **renal disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray*	No	No	No	▨
ECG†	No	▨	▨	▨
Full blood count	▨	▨	▨	▨
Haemostasis	No	No	No	No
Renal function	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No
Urine analysis	▨	▨	▨	▨
Blood gases	No	No	No	No
Lung function	No	No	No	No

*Chest X-ray may be considered if the patient has signs of other comorbidities often associated with renal disease, such as hypertension and coronary heart failure

†Depending on the cause of renal disease (e.g. diabetes and hypertension)

ASA Grade 3: adults with comorbidity from **renal disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray*	No	No	▨	▨
ECG	No	▨	▨	▨
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes
Random glucose	▨	▨	▨	▨
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	No	No	No	No

*Chest X-ray may be considered if the patient has signs of other comorbidities often associated with renal disease, such as hypertension and coronary heart failure

Grade 2 surgery (intermediate)

ASA Grades

Grade 1 Normal healthy patient (i.e. without any clinically important comorbidity and without a clinically significant past/present medical history).

Grade 2 Patient with mild systemic disease

Grade 3 A patient with severe systemic disease but the disease is not a constant threat to life.

See Boxes 2 and 3 for more information

- ● Test not recommended
- ◍ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).
- ○ Test recommended

ASA Grade 1: children < 16 years

Test	Age				
	< 6 months	≥ 6 to < 12 months	≥ 1 to < 5 years	≥ 5 to < 12 years	≥ 12 to < 16 years
Chest X-ray	No	No	No	No	No
ECG	No	No	No	No	No
Full blood count	No	No	No	No	No
Haemostasis	No	No	No	No	No
Renal function	No	No	No	No	No
Random glucose	No	No	No	No	No
Urine analysis*	No	No	No	No	No

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 1: adults ≥ 16 years

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	No	No	No	No
ECG	No	◍	◍	Yes
Full blood count	No	◍	Yes	Yes
Haemostasis	No	No	No	No
Renal function	No	No	◍	◍
Random glucose	No	◍	◍	◍
Urine analysis*	◍	◍	◍	◍

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 2: adults with comorbidity from cardiovascular disease

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	◍	◍	◍	◍
ECG	Yes	Yes	Yes	Yes
Full blood count	◍	◍	◍	◍
Haemostasis	No	No	No	No
Renal function	◍	◍	Yes	Yes
Random glucose	No	No	No	No
Urine analysis	◍	◍	◍	◍
Blood gases	No	No	No	No
Lung function	No	No	No	No

ASA Grade 3: adults with comorbidity from cardiovascular disease

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	◍	◍	◍	◍
ECG	Yes	Yes	Yes	Yes
Full blood count	◍	◍	◍	◍
Haemostasis	No	No	No	No
Renal function	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No
Urine analysis	◍	◍	◍	◍
Blood gases	◍	◍	◍	◍
Lung function	No	No	No	No

Grade 2 surgery (intermediate) continued

ASA Grades

Grade 1 Normal healthy patient (i.e. without any clinically important comorbidity and without a clinically significant past/present medical history).

Grade 2 Patient with mild systemic disease

Grade 3 A patient with severe systemic disease but the disease is not a constant threat to life.

See Boxes 2 and 3 for more information

● Test not recommended

◍ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

ASA Grade 2: adults with comorbidity from **respiratory disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	◍	◍	◍	◍
ECG	No	◍	◍	◍
Full blood count	◍	◍	◍	◍
Haemostasis	No	No	No	No
Renal function	No	◍	◍	◍
Random glucose	No	No	No	No
Urine analysis	◍	◍	◍	◍
Blood gases	◍	◍	◍	◍
Lung function	No	No	No	No

ASA Grade 3: adults with comorbidity from **respiratory disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	◍	◍	◍	◍
ECG	◍	◍	Yes	Yes
Full blood count	◍	◍	◍	Yes
Haemostasis	No	No	No	No
Renal function	◍	◍	◍	◍
Random glucose	No	No	No	No
Urine analysis	◍	◍	◍	◍
Blood gases	◍	◍	◍	◍
Lung function	◍	◍	◍	◍

ASA Grade 2: adults with comorbidity from **renal disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray*	No	No	◍	◍
ECG†	◍	◍	Yes	Yes
Full blood count	◍	◍	◍	◍
Haemostasis	No	No	No	No
Renal function	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No
Urine analysis	◍	◍	◍	◍
Blood gases	No	No	No	No
Lung function	No	No	No	No

*Chest X-ray may be considered if the patient has signs of other comorbidities often associated with renal disease, such as hypertension and coronary heart failure

†Depending on the cause of renal disease (e.g. diabetes and hypertension)

ASA Grade 3: adults with comorbidity from **renal disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	◍	◍	◍	◍
ECG	◍	◍	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	◍	◍	◍	◍
Renal function	Yes	Yes	Yes	Yes
Random glucose	◍	◍	◍	◍
Urine analysis	◍	◍	◍	◍
Blood gases	◍	◍	◍	◍
Lung function	No	No	No	No

Grade 3 surgery (major)

ASA Grades

Grade 1 Normal healthy patient (i.e. without any clinically important comorbidity and without a clinically significant past/present medical history).

Grade 2 Patient with mild systemic disease

Grade 3 A patient with severe systemic disease but the disease is not a constant threat to life.

See Boxes 2 and 3 for more information

● Test not recommended

▨ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

ASA Grade 1: children < 16 years

Test	Age				
	< 6 months	≥ 6 to < 12 months	≥ 1 to < 5 years	≥ 5 to < 12 years	≥ 12 to < 16 years
Chest X-ray	No	No	No	No	No
ECG	No	No	No	No	No
Full blood count	▨	▨	▨	▨	▨
Haemostasis	No	No	No	No	No
Renal function	▨	▨	▨	▨	▨
Random glucose	No	No	No	No	No
Urine analysis*	▨	▨	▨	▨	▨

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 1: adults ≥ 16 years

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	No	No	▨	▨
ECG	No	▨	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	No	No	No	No
Renal function	▨	▨	Yes	Yes
Random glucose	▨	▨	▨	▨
Urine analysis*	▨	▨	▨	▨

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 2: adults with comorbidity from **cardiovascular disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG	Yes	Yes	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	No	No	No	No
Renal function	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	No	No	No	No

ASA Grade 3: adults with comorbidity from **cardiovascular disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG	Yes	Yes	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	No	No	No	No

Grade 3 surgery (major) continued

ASA Grades

Grade 1 Normal healthy patient (i.e. without any clinically important comorbidity and without a clinically significant past/present medical history).

Grade 2 Patient with mild systemic disease

Grade 3 A patient with severe systemic disease but the disease is not a constant threat to life.

See Boxes 2 and 3 for more information

● Test not recommended

▨ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

ASA Grade 2: adults with comorbidity from **respiratory disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG	▨	▨	▨	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	No	No	No	No
Renal function	▨	▨	Yes	Yes
Random glucose	No	No	No	No
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	No	▨	▨	▨

ASA Grade 3: adults with comorbidity from **respiratory disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG	▨	▨	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	No	No	No	No
Renal function	Yes	Yes	Yes	Yes
Random glucose	▨	▨	▨	▨
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	▨	▨	▨	▨

ASA Grade 2: adults with comorbidity from **renal disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG[†]	▨	▨	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes
Random glucose	▨	▨	▨	▨
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	No	No	No	No

[†] Depending on the cause of renal disease (e.g. diabetes and hypertension)

ASA Grade 3: adults with comorbidity from **renal disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG	▨	▨	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes
Random glucose	▨	▨	▨	▨
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	No	No	No	No

Grade 4 surgery (major+)

ASA Grades

Grade 1 Normal healthy patient (i.e. without any clinically important comorbidity and without a clinically significant past/present medical history).

Grade 2 Patient with mild systemic disease

Grade 3 A patient with severe systemic disease but the disease is not a constant threat to life.

See Boxes 2 and 3 for more information

● Test not recommended

◍ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

ASA Grade 1: children < 16 years

Test	Age				
	< 6 months	≥ 6 to < 12 months	≥ 1 to < 5 years	≥ 5 to < 12 years	≥ 12 to < 16 years
Chest X-ray	No	No	No	No	No
ECG	No	No	No	No	No
Full blood count	◍	◍	◍	◍	◍
Haemostasis	No	No	No	No	No
Renal function	◍	◍	◍	◍	◍
Random glucose	No	No	No	No	No
Urine analysis*	◍	◍	◍	◍	◍

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 1: adults ≥ 16 years

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	No	No	◍	◍
ECG	No	◍	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	◍	◍	◍	◍
Renal function	Yes	Yes	Yes	Yes
Random glucose	◍	◍	◍	◍
Urine analysis*	◍	◍	◍	◍

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 2: adults with comorbidity from **cardiovascular disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	◍	◍	◍	◍
ECG	Yes	Yes	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	◍	◍	◍	◍
Renal function	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No
Urine analysis	◍	◍	◍	◍
Blood gases	◍	◍	◍	◍
Lung function	No	No	No	No

ASA Grade 3: adults with comorbidity from **cardiovascular disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	◍	◍	Yes	Yes
ECG	Yes	Yes	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	◍	◍	◍	◍
Renal function	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No
Urine analysis	◍	◍	◍	◍
Blood gases	◍	◍	◍	◍
Lung function	No	No	No	No

Grade 4 surgery (major+) continued

ASA Grades

Grade 1 Normal healthy patient (i.e. without any clinically important comorbidity and without a clinically significant past/present medical history).

Grade 2 Patient with mild systemic disease

Grade 3 A patient with severe systemic disease but the disease is not a constant threat to life.

See Boxes 2 and 3 for more information

● Test not recommended

◐ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

ASA Grade 2: adults with comorbidity from **respiratory disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG	▨	▨	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	▨	▨	▨	▨

ASA Grade 3: adults with comorbidity from **respiratory disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG	▨	Yes	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes
Random glucose	▨	▨	▨	▨
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	▨	▨	▨	▨

ASA Grade 2: adults with comorbidity from **renal disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG[†]	▨	Yes	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes
Random glucose	▨	▨	▨	▨
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	No	No	No	No

[†] Depending on the cause of renal disease (e.g. diabetes and hypertension)

ASA Grade 3: adults with comorbidity from **renal disease**

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	▨	▨	▨	▨
ECG	▨	Yes	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes
Random glucose	▨	▨	▨	▨
Urine analysis	▨	▨	▨	▨
Blood gases	▨	▨	▨	▨
Lung function	No	No	No	No

Neurosurgery

ASA Grades

Grade 1 Normal healthy patient (i.e. without any clinically important comorbidity and without a clinically significant past/present medical history).

Grade 2 Patient with mild systemic disease

Grade 3 A patient with severe systemic disease but the disease is not a constant threat to life.

See Boxes 2 and 3 for more information

● Test not recommended

◍ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

SA Grade 1: children < 16 years

Test	Age				
	< 6 months	≥ 6 to < 12 months	≥ 1 to < 5 years	≥ 5 to < 12 years	≥ 12 to < 16 years
Chest X-ray	No	No	No	No	No
ECG	No	No	No	No	No
Full blood count	▨	▨	▨	▨	▨
Haemostasis	▨	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No	No
Urine analysis*	▨	▨	▨	▨	▨

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 1: adults ≥ 16 years

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	No	No	▨	▨
ECG	▨	▨	Yes	Yes
Full blood count	▨	▨	Yes	Yes
Haemostasis	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes
Random glucose	▨	▨	▨	▨
Urine analysis*	▨	▨	▨	▨

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

Cardiovascular surgery

ASA Grades

Grade 1 Normal healthy patient (i.e. without any clinically important comorbidity and without a clinically significant past/present medical history).

Grade 2 Patient with mild systemic disease

Grade 3 A patient with severe systemic disease but the disease is not a constant threat to life.

See Boxes 2 and 3 for more information

● Test not recommended

◍ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

ASA Grade 1: children < 16 years

Test	Age				
	< 6 months	≥ 6 to < 12 months	≥ 1 to < 5 years	≥ 5 to < 12 years	≥ 12 to < 16 years
Chest X-ray	Yes	Yes	Yes	Yes	Yes
ECG	Yes	Yes	Yes	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes	Yes
Haemostasis	▨	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes	Yes
Random glucose	No	No	No	No	No
Urine analysis*	▨	▨	▨	▨	▨

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

ASA Grade 1: adults ≥ 16 years

Test	Age (years)			
	≥ 16 to < 40	≥ 40 to < 60	≥ 60 to < 80	≥ 80
Chest X-ray	Yes	Yes	Yes	Yes
ECG	Yes	Yes	Yes	Yes
Full blood count	Yes	Yes	Yes	Yes
Haemostasis	▨	▨	▨	▨
Renal function	Yes	Yes	Yes	Yes
Random glucose	▨	▨	▨	▨
Urine analysis*	▨	▨	▨	▨

*Dipstick urine testing in asymptomatic individuals is not recommended (UK National Screening Committee)

TESTS FOR THE SICKLE CELL GENE IN ADULTS AND CHILDREN

Appropriateness of testing in patients from the following ethnic groups	
North African	Yes
West African	Yes
South/sub Saharan African	Yes
Afro Caribbean	Yes
Should informed consent be obtained?	**Yes**

● Test not recommended

▨ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

Notes

- It is important to offer to test all patients in these ethnic groups, and people of other ethnic groups considered to be at risk. The sickle cell gene is found in many nationalities including families that come from Africa, the Caribbean, the Eastern Mediterranean, Middle East and Asia. It has also been detected in Cypriot people and a few other white ethnic groups.
- It is important to offer to test patients before they have an anaesthetic, if there is any uncertainly about whether they have the sickle cell gene. This is especially important for patients who have a family history of homozygous sickle cell anaemia or sickle cell trait and who do not have a surgical history where it may have been detected previously.
- People of ethnic origin considered to be at risk should be offered screening, with genetic counselling before and after screening.
- Some patients may not know their ethnicity, for example those who have been adopted.
- Appropriate counselling for this test is important so that patients are able to give their informed consent, as there may be implications for patients who discover they are carriers of the sickle cell gene. The results of testing, even when negative, should be reported to families and

documented in the patient's medical record to avoid unnecessary repeat testing. Counselling should be offered if the result of the test if positive.

PREGNANCY TEST

Pregnancy testing should be carried out in the following female patients of reproductive age:	
With history of last menstrual period	▨
Who says that it is not possible for her to be pregnant	▨
Who says it is possible that she may be pregnant	Yes
Should informed consent be obtained	**Yes**

● Test not recommended

▨ Test to be considered (the value of carrying out a preoperative test is not known, and may depend on specific patient characteristics).

○ Test recommended

Notes

- The need to test for pregnancy depends on the risk presented by the anaesthetic and surgery to the fetus. All women of child-bearing age should be asked whether or not there is any chance that they may be pregnant.
- Women must be made aware of the risks of surgery to the fetus.
- A pregnancy test should be carried out with the woman's consent if there is any doubt about whether the woman may be pregnant.
- Before having a chest X-ray, all women of child-bearing age should be asked sensitively whether they may be pregnant.

PATIENT CONSENT

- The issue of consent to undergo preoperative tests is addressed briefly in relation to specific tests in Chapters 4–7 of the full version of the guideline (available on the NICE website www.nice.org.uk). For further guidance, clinicians should refer to the *Good Practice in Consent* guidance on issues of consent in the NHS (Department of Health [2002] *Good practice in Consent Implementation Guide: Consent to Examination or Treatment.* Available from: www.doh.gov.uk/consent).

- This guideline supports the advice given in that publication – that it is “a general legal and ethical principle that valid consent must be obtained before starting treatment or physical examination, or providing personal care, for a patient” and that patients should have access to sufficient information about risks, benefits and alternatives to be able to make an informed decision about whether to consent.
- Staff undertaking clinical preoperative assessments should discuss with patients which tests are recommended (or required), what they involve and why they are being carried out.
- Decisions about whether to test or not should follow discussion between the patient and the doctor or nurse, especially where there is uncertainty about whether a test should be recommended or not. For some tests, a positive result carries a far greater significance for the patient than others, such as testing for previously undetected diabetes, the sickle cell gene and pregnancy.
- Patients should have access to information about the tests and the possible implications of a positive result so that they can give their informed consent. Doctors or nurses carrying out or ordering tests should write in the patient’s notes that they have discussed the recommended tests and their implications with the patient.
- Patients should be informed of the results of tests and about the implications for treatment, and any longer term implications for their health, if the results are abnormal.

TECHNOLOGY APPRAISAL

Ultrasound locating devices for placing central venous catheters

Issue date – September 2002 **Review date** – August 2005

Two-dimensional (2-D) imaging ultrasound guidance is recommended as the preferred method for insertion of central venous catheters (CVCs) into the internal jugular vein (IJV) in adults and children in elective situations.

The use of two-dimensional (2-D) imaging ultrasound guidance should be considered in most clinical circumstances where CVC insertion is necessary either electively or in an emergency situation.

It is recommended that all those involved in placing CVCs using two-dimensional (2-D) imaging ultrasound guidance should undertake appropriate training to achieve competence.

Audio-guided Doppler ultrasound guidance is not recommended for CVC insertion.

Appendix A:
Forward work programme – Clinical Guidelines

Clinical Guideline	Issued to the NHS
Multiple sclerosis	November 2003
Eating disorders	January 2004
Footcare (update)	January 2004
Chronic obstructive pulmonary disease	February 2004
Familial breast cancer	February 2004
Fertility	February 2004
Dyspepsia	March 2004
Hypertension	March 2004
Management of depression	March 2004
Caesarean section	April 2004
Self harm	May 2004
Anxiety (generalised)	June 2004
Epilepsy	June 2004
Dental recall	August 2004
Falls	August 2004
Disturbed (violent) behaviour	November 2004
Lung cancer	November 2004
Post traumatic stress disorder (PTSD)	January 2005
Long-acting reversible contraception	February 2005
Referral guidelines for suspected cancer	February 2005
Tuberculosis	March 2005
Depression in children	April 2005
Diabetes type 1	May 2005
Pressure ulcer (management)	May 2005

Clinical Guideline	Issued to the NHS
Management and delivery of care to women in labour (intrapartum care)	June 2005
Obsessive compulsive disorder	June 2005
Osteoporosis	June 2005
Parkinson's disease	July 2005
Hysterectomy and alternative interventions	November 2005
Management of urinary incontinence and prolapse of the womb	November 2005
Nutritional supplements	December 2005
Management of bipolar affective disorder (manic-depressive illness)	TBC
Management of dementia, including use of antipsychotic medication in people with dementia	TBC
Management of surgical wounds	TBC
Obesity	TBC
Routine post natal care of recently delivered women and their babies	TBC
Venous thrombo-embolism	TBC

Service Guidance

Guideline	Issued to the NHS
Supportive and palliative cancer care	February 2004
Colorectal cancer (update)	January 2004
Head and neck cancer	July 2004
Child and adolescent cancer	January 2005
Skin tumours including melanoma	April 2005

TBC – To be confirmed

Guideline	Issued to the NHS
Tumours of the brain and central nervous system	June 2005
Sarcoma	July 2005

Forward work programme – Interventional Procedures

Procedure name	Issued to the NHS
Endoscopic dacryocystorhinostomy	February 2004
KTP laser (60-80W) vaporisation of the prostate for benign prostatic obstruction	February 2004
Needle fasciotomy for Dupuytren's contracture	February 2004
Partial left ventriculectomy	February 2004
Extracorporeal membrane oxygenation (adult)	March 2004
Endoscopic injection of a biopolymer for gastro-oesophageal reflux disease	March 2004
Image guided (CT) thermocoagulation of osteoid osteoma	March 2004
Percutaneous radiofrequency ablation of renal cancer	March 2004
Selective internal radiation therapy for hepatic metastases	March 2004
Artificial anal sphincter	Spring 2004
Bone-anchored cystourethropexy (In-tac and Vesica)	Spring 2004
Extracorporeal albumin dialysis for acute on chronic liver disease	Spring 2004
Free fluid thermal endometrial ablation	Spring 2004
Hysteroscopic laser myomectomy	Spring 2004

Procedure name	Issued to the NHS
Laparoscopic helium plasma coagulation of endometriosis	Spring 2004
Laparoscopic total hysterectomy	Spring 2004
Macular translocation for age-related macular degeneration	Spring 2004
Photodynamic endometrial ablation for menorrhagia	Spring 2004
Radiotherapy in macular degeneration	Spring 2004
Sugarbaker technique for pseudomyxoma peritonei	Spring 2004
Supraorbital minicraniotomy for intracranial aneurysm	Spring 2004
Vagus nerve stimulation for refractory epilepsy in children	Spring 2004
Artificial joints for osteoarthritis of the hand	Summer 2004
Electropalatography	Summer 2004
High flow interposition extracranial to intracranial bypass	Summer 2004
Hysteroscopic sterilisation by tubal canulation and placement of intrafallopian implant	Summer 2004
Laparoscopic live donor simple nephrectomy	Summer 2004
Percutaneous endoscopic laser thoracic discectomy	Summer 2004
Wireless capsule endoscopy for obscure gastrointestinal bleeding and suspected Crohn's disease	Summer 2004
Sheathotomy for occlusion of macular branch retinal veins	Summer 2004
Impedance controlled endometrial ablation for heavy menstrual bleeding	Summer 2004

Procedure name	Issued to the NHS
High intensity focused ultrasound for prostate cancer	Summer 2004
Gastro electro mechanical stimulation for gastroparesis	Summer 2004
Photodynamic therapy for high-grade dysplasia for Barrett's oesophagus	Summer 2004
Balloon angioplasty of caval vein stenosis	TBC
Balloon dilation of pulmonary valve stenosis	TBC
Balloon or blade atrial septostomy	TBC
Balloon valvuloplasty for aortic valve stenosis	TBC
Endovascular closure of patent arterial duct	TBC
Endoscopic axillary lymph node retrieval	TBC
Endoscopic epidural procedures	TBC
Endoscopic laser foraminoplasty (ELF)	TBC
Falloposcopy with coaxial catheter	TBC
Interstitial laser therapy for breast cancer	TBC
Laparoscopic pyeloplasty	TBC
Laser assisted serial tonsillectomy	TBC
Laser/radiofrequency valvotomy for pulmonary atresia	TBC
Laser sheath removal of pacing leads	TBC
Lumbar subcutaneous shunt	TBC
Non surgical reduction myocardial septum	TBC
Photodynamic therapy for superficial bronchial cancer	TBC
Primary auditory brain stem implants	TBC
Secondary transperineal cryotherapy for carcinoma of prostate	TBC

TBC – To be confirmed

Procedure name	Issued to the NHS
Stent-graft placement in thoracic aorta	TBC
Stent placement in the right ventricular outflow tract	TBC
Subfascial Endoscopic Perforator vein surgery for varicose veins	TBC
Subthalamotomy for Parkinson's disease	TBC
Therapeutic selective salpingography: guide-wire	TBC
Thrombin injection of pseudoaneurysms	TBC
Transpupillary thermotherapy for age-related macular degeneration	TBC

Forward work programme – Technology Appraisals

Technology Appraisals	Issued to the NHS*
New drugs for bi-polar disorder	August 2003
Amantadine and oseltamivir for prophylaxis of influenza	September 2003
Rituximab for aggressive non-Hodgkin's lymphoma	September 2003
Drug eluting stents for prevention of restenosis and coronary artery stents for ischaemic heart disease (review)	October 2003
Imatinib for first line treatment of chronic myeloid leukaemia	October 2003
Liquid based cytology for cervical screening (review)	October 2003
Anakinra for rheumatoid arthritis	November 2003
Newer drugs for epilepsy (adult)	November 2003

* Dates are provisional and subject to any appeal. Please check the NICE website for details www.nice.org.uk
TBC – To be confirmed

Technology Appraisals	Issued to the NHS*
Newer drugs for epilepsy (children)	November 2003
Coronary imaging for angina and myocardial infarction	November 2003
Pegylated interferons, ribavirin and alpha interferon for hepatitis C (part review)	November 2003
Pre-hospital intravenous fluid therapy for trauma	January 2004
Newer hypnotic drugs for insomnia	March 2004
Immuno-suppressive regimens for renal transplantation	April 2004
Imatinib (Glivec) for gastro-intestinal stromal tumours	May 2004
Clopidogrel and dipyramidole for occusive vascular events	June 2004
Clopidogrel for acute coronary syndromes	June 2004
Prevention and treatment of osteoporosis	June 2004
Topical steroids in atopic dermatitis (eczema)	July 2004
Cannabinoids for symptoms of multiple sclerosis	August 2004
Drotecogin (Xigris) for severe sepsis	August 2004
Pimecrolimus (Elidel) and tacrolimus (Protopic) for atopic dermatitis (eczema)	September 2004
Gefitinib (Iressa) for non-small cell lung cancer	November 2004
New treatments for diabetic foot ulcers	November 2004
New treatments for venous leg ulcers	December 2004
Dual chamber pacing	January 2005
New pharmaceutical treatments for non-Alzheimer dementias	March 2005

* Dates are provisional and subject to any appeal. Please check the NICE website for details www.nice.org.uk.

Technology Appraisals	Issued to the NHS*
New treatments for moderate to severe psoriasis	March 2005
Drugs for moderate to severe Alzheimer's disease	May 2005
Endometrial ablation for menorrhagia	TBC
Hormonal treatments for early breast cancer	TBC
Omalizumab (Xolair) for uncontrolled asthma	TBC
Parent training programmes, for treatment and prevention of conduct disorder	TBC
Statins for prevention of coronary events	TBC

Other Guidance

Guideline	Issued to the NHS
Guidance on identification, prevention and management of obesity and maintenance of weight reduction	TBC
Guidance on reduction in accidental injuries outside the home	TBC
Patient safety guide on prevention of venous thrombo-embolism in patients undergoing orthopaedic surgery and other high-risk surgical procedures	TBC

TBC – To be confirmed

Appendix B – Appraisal Committee

The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. The Appraisal Committee meets twice a month except in December, when there are no meetings. The Committee membership is split into two branches, with the chair, vice-chair and a number of other members attending meetings of both branches. Each branch considers its own list of technologies and ongoing topics are not moved between the branches.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Dr Jane Adam
Radiologist, St George's Hospital, London

Dr A E Ades
MRC Senior Scientist, MRC Health Services Research Collaboration, Department of Social Medicine, University of Bristol

Professor Ron Akehurst
Dean, School of Health Related Research, University of Sheffield

Dr Sunil Angris
General Practitioner, Waterhouses Medical Practice, Staffordshire

Dr Tom Aslan
General Practitioner, Stockwell, London

Dr Darren Ashcroft
Senior Clinical Lecturer, School of Pharmacy and Pharmaceutical Sciences, University of Manchester

Professor David Barnett (Chair)
Professor of Clinical Pharmacology, University of Leicester

Dr Sheila Bird
MRC Biostatistics Unit, Cambridge

Professor John Brazier
Health Economist, University of Sheffield

Professor Rosamund Bryar
Professor of Community & Primary Care Nursing,
St Bartholomew's School of Nursing & Midwifery, London

Professor John Cairns
Professor of Health Economics, Health Economics Research Unit,
Institute of Applied Health Sciences, University of Aberdeen

Dr Mark Chakravarty
Head of Government Affairs and NHS Policy, Proctor and
Gamble Pharmaceuticals (UK) Ltd, Surrey

Dr Peter Clark
Consultant Medical Oncologist, Clatterbridge Centre for
Oncology, Wirral

Professor Mike Campbell
Statistician, Institute of General Practice & Primary Care,
Sheffield

Dr Karl Claxton
Health Economist, University of York

Dr Richard Cookson
Senior Lecturer, Health Economics, School of Health Policy and
Practice, University of East Anglia, Norwich

Dr Mike Davies
Consultant Physician, University Department of Medicine &
Metabolism, Manchester Royal Infirmary

Dr Cam Donaldson
PPP Foundation Professor of Health Economics, School of
Population and Health Sciences & Business School, Business
School – Economics, University of Newcastle upon Tyne

Professor Jack Dowie
Health Economist, London School of Hygiene and Tropical Medicine

Dr Paul Ewings
Statistician, Taunton & Somerset NHS Trust, Taunton

Professor Terry Feest
Clinical Director & Consultant Nephrologist, Richard Bright Renal Unit, & Chair of UK Renal Registry, Bristol

Professor Gary A Ford
Professor of Pharmacology of Old Age/Consultant Physician, Newcastle upon Tyne Hospitals NHS Trust

Professor John Geddes
Professor of Epidemiological Psychiatry, University of Oxford

Ms Bethan George
Interface Liaison Pharmacist, Tower Hamlets PCT and Royal London Hospital, Whitechapel

Dr Trevor Gibbs
Head, Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline, Greenford

Ms Sally Gooch
Director of Nursing, Mid-Essex Hospital Services NHS Trust, Chelmsford

Mr John Goulston
Director of Finance, St Bartholoemew's Hospital & the London NHS Trust

Professor Trisha Greenhalgh
Professor of Primary Health Care, University College London

Miss Linda Hands
Clinical Reader in Surgery, University of Oxford

Professor Philip Home
Professor of Diabetes Medicine, University of Newcastle upon Tyne

Dr Terry John
General Practitioner, The Firs, London

Professor Robert Kerwin
Professor of Psychiatry and Clinical Pharmacology, Institute of Psychiatry, London

Ms Ruth Lesirge
Lay Representative; previously Director, Mental Health Foundation, London

Dr George Levvy
Lay Representative; Chief Executive, Motor Neurone Disease Association, Northampton

Dr Gill Morgan
Chief Executive, NHS Confederation, London

Mr Muntzer Mughal
Consultant Surgeon, Lancashire Teaching Hospitals NHS Trust, Chorley

Mr James Partridge
Lay Representative; Chief Executive, Changing Faces, London

Mrs Kathryn Roberts
Nurse Practitioner, Hyde, Cheshire

Professor Philip Routledge
Professor of Clinical Pharmacology, College of Medicine, University of Wales, Cardiff

Dr Stephen Saltissi
Consultant Cardiologist, Royal Liverpool University Hospital

Mr Miles Scott
Chief Executive, Harrogate Health Care NHS Trust

Ms Anne Smith
Lay Representative; Trustee, Long-Term Medical Conditions Alliance

Professor Andrew Stevens (Vice-Chair)
Professor of Public Health, University of Birmingham

Dr Cathryn Thomas
General Practitioner, & Senior Lecturer, Department of Primary Care & General Practice, University of Birmingham

Dr Norman Vetter
Reader, Department of Epidemiology, Statistics and Public Health, College of Medicine, University of Wales, Cardiff

Professor Mary Watkins
Professor of Nursing, University of Plymouth

Dr Norman Waugh
Department of Public Health, University of Aberdeen

Dr David Winfield
Consultant Haematologist, Royal Hallamshire Hospital, Sheffield

Appendix C: Guideline Review Panels

The Guideline Review Panels consist of 4–5 members and include a separate chair and deputy. Each is aligned with a National Collaborating Centre (NCC) that manages the development of clinical guidelines for NICE.The panels are responsible for validating the final full guideline, paying particular attention to the guideline developers' responses to stakeholder comments received during the course of the consultation process.

Each panel will be able to bring in additional statistical or methodological support as required and panel members will meet two or three times a year within a learning forum in order to share experiences and be updated regarding guideline methodology and new developments within the NCCs.

NCC FOR WOMEN & CHILDREN'S HEALTH

Miss Helen Spiby
Senior Lecturer (Evidence Based Practice in Midwifery)
Mother and Infant Research Unit
University of Leeds

Dr Marcia Kelson
Director
Patient Involvement Unit (PIU) for NICE

Mrs Carol Youngs
Patient representative

Dr Monica Lakhanpaul
Senior Lecturer in Child Health/Consultant Paediatrician,
Leicester

Mr Vincent Argent
Consultant Obstetrician and Gynaecologist
Eastbourne District General Hospital

Dr Jenny Tyrrell
General Paediatrician
Royal United hospital
Bath

Mrs Christine Oppenheimer
Consultant Obstetrician & Gynaecologist
Leicester Royal Infirmary

NCC FOR CHRONIC CONDITIONS

Dr Bernard Higgins
Consultant chest physician
Newcastle

Dr Marcia Kelson
Director
Patient Involvement Unit (PIU) for NICE

Dame Helena Shovelton
Patient representative

Dr Peter Rutherford
Senior Lecturer in Nephrology/Medical Director
University of Wales College of Medicine

Dr Robert Higgins
Consultant in Renal and General Medicine
University Hospital, Coventry & Warwickshire

Mrs Fiona Wise
Chief Executive
Ealing Hospitals NHS Trust

Dr John Young
Medical Director, MSD

NCC FOR CANCER

Dr John Hyslop
Consultant Radiologist
Royal Cornwall Hospital NHS Trust

Dr Marcia Kelson
Director
Patient Involvement Unit (PIU) for NICE

Mr Peter Madeley
Patient representative

Dr Stephen Karp
Consultant Clinical Oncologist
North Middlesex Hospital

Mr Mark Emberton
Clinical Effectiveness Unit
Royal College of Surgeons

David Sommerville
Industry Representative

Martin Ward
Director of Medical Operations
Novartis Pharma Ltd

NCC FOR MENTAL HEALTH

Dr Chaand Nagpaul
General Practitioner
Stanmore

Dr Marcia Kelson
Director
Patient Involvement Unit (PIU) for NICE

Mr John Seddon
Patient representative

Professor Kenneth Wilson
Professor of Psychiatry of Old Age
University of Liverpool

Professor Shirley Reynolds
Professor of Clinical Psychology
University of East Anglia

Roger Paxton
Director of Psychological Services
Research & Development
Newcastle, North Tyneside & Northumberland Mental Health NHS Trust

NCC FOR ACUTE CARE

Mr Peter Robb
Consultant ENT Surgeon
Epsom & St Helier & Royal Surrey NHS Trust

Dr Marcia Kelson
Director
Patient Involvement Unit (PIU) for NICE

Mrs Joyce Struthers
Patient representative

Dr Peter Duncan
Consultant in Anaesthetics and Intensive Care Medicine
Royal Preston Hospital

Mrs Anne Williams
Assistant Director of Clinical Governance
Kettering General Hospital NHS Trust

NCC FOR PRIMARY CARE

Professor Mike Drummond
Director
Centre for Health Economics (CHE)
University of York

Marcia Kelson
Director
Patient Involvement Unit (PIU) for NICE

Mr Barry Stables
Patient representative

Dr Imogen Stephens
Joint Director of Public health
West Sussex PCT

Kev Hopayian
General Practitioner
Leiston

Dr Robert Walker
Clinical Director
West Cumbria PCT

NCC FOR NURSING & SUPPORTIVE CARE

Mrs Judy Mead
Head of Clinical Effectiveness
Chartered Society of Physiotherapy

Dr Marcia Kelson
Director
Patient Involvement (PIU) for NICE

Joyce Cormie
Patient representative

Mrs Gill Hek
Principal lecturer
University of West of England

Mrs Karen Cowley
Practice Development Nurse
York Hospital

Mrs Jill Freer
Head of Clinical Governance and Quality Development
Leicestershire, Northamptonshire and Rutland Strategic Health Authority

Miss Amanda Wilde
Reimbursements and Outcomes manager
Convatec Ltd

Appendix D: Interventional Procedures Advisory Committee

NICE guidance on interventional procedures is developed by an independent Interventional Procedures Advisory Committee (IPAC) made up of professionals working in the NHS and people who are familiar with the issues affecting patients and carers. The committee is chaired by Professor Bruce Campbell and meets monthly.

Professor Bruce Campbell
Consultant Vascular and General Surgeon, Royal Devon and Exeter Hospital

Professor Paul Abrams
Consultant Urological Surgeon, Bristol Urological Institute

Mr Alan Bartle
Chief Executive, The Migraine Trust

Dr Anna-Marie Belli
Consultant Radiologist, St Georges Hospital

Dr Christopher Bunch, Vice Chairman of IPAC
Consultant Physician and Hon Senior Lecturer, Oxford Radcliffe Hospitals NHS Trust, and Chairman of the British Association of Medical Managers

Mr Stephen Cannon
Consultant Orthopaedic Surgeon, Royal National Orthopaedic Hospital

Dr Roger Chapman
Consultant Gastroenterologist, Oxford Radcliffe Trust

Ms Sheena Cumiskey
Chief Executive Wrightington, Wigan and Leigh NHS Trust

Dr Keith Dawkins
Consultant Cardiologist, Wessex Cardiothoracic Centre (NHS)

Mr Tony De Souza
Consultant Cardiothoracic Surgeon, Royal Brompton Hospital

Dr Adrian Freeman
General Practitioner, St Leonard's Medical Practice, Exeter

Mr David Hay
Consultant General Surgeon at Glan Clwyd Hospital, North Wales

Mr Paul Hilton
Consultant Gynaecologist Royal Victoria Infirmary, Newcastle

Dr Roop Kishen
Consultant Intensivist, Hope Hospital Salford

Dr Susanne Ludgate
Medical Director of the MHRA

Professor Gordon Murray
Professor of Medical Statistics, University of Edinburgh Medical School

Dr Eileen Scott
Research & Development Co-ordinator, North Tees & Hartlepool NHS Trust

Dr Sandeep Shah
Medical Director, SSL International Ltd

Mr Barrie White
Consultant Neurosurgeon, Queen's Medical Centre, Nottingham

Dr Merran Thomson
Consultant Paediatrician, Hammersmith Hospital

Mr Simon Williams
Director of Policy, The Patients Association

Professor Charles Wolfe
Professor of Public Health Medicine, Guy's, King's & St Thomas' Hospitals School of Medicine

Professor Kent Woods
Director NCCHTA

Appendix E: Technology Appraisal Process – Summary

1. The Department of Health and the Welsh Assembly Government select technologies for appraisal by NICE. They use one or more of these criteria:
   - Is the technology likely to result in a significant health benefit, across the NHS as a whole, if given to all relevant patients?
   - Is the technology likely to result in a significant impact on other health-related government policies, such as reduction in health inequalities?
   - Is the technology likely to result in a significant impact on NHS resources (financial or other) if given to all relevant patients?

Also, is NICE likely to be able to add value by issuing national guidance? For instance, might there otherwise be controversy over the available evidence on clinical and cost effectiveness?

2. A technology can be in one of the following categories:
   - pharmaceutical
   - medical device
   - diagnostic technique
   - surgical procedure
   - other therapeutic intervention
   - health promotion
3. The Institute will appraise 30–50 technologies per year.
4. The process the Institute follows for appraisals was developed after consultation and is the same for each technology appraisal. Full details are published on the NICE web site (www.nice.org.uk). In summary:
   - The Institute develops the scope for the appraisal in consultation with the national bodies that represent health professionals, national patient/carer organisations and the manufacturers/sponsors of the technology.
   - NICE commissions an assessment report, which is a critical review of the evidence on the clinical and cost

effectiveness of the technology. At the same time the Institute invites submissions from the relevant manufacturers, the national organisations representing patients/carers and the national health professional bodies working in the field. The assessment report will draw, as appropriate, on the submissions from manufacturers/ sponsors.

- This evidence is combined in an evaluation report and submitted to the Appraisal Committee. The Appraisal Committee is a combination of patient advocates, NHS clinicians and managers, academic experts and industry representatives, who are appointed for three years. Technology-specific 'experts for the day' are invited to individual meetings to inform the Committee. These experts include healthcare professionals and patient/carer representatives and they bring valuable first hand knowledge to the Committee's work.
- The Committee produces an appraisal consultation document (ACD) which is circulated to all consultees for a period of 4 weeks' consultation. At this stage the Institute also consults with the Department of Health and the National Assembly for Wales, and posts the ACD on its web site.
- The Appraisal Committee meets again and considers the original evidence in light of the consultation feedback. Following this meeting the Committee produces a final appraisal determination (FAD). All consultees then have the opportunity to make an appeal against the FAD. The FAD is also published on the Institute's web site.
- Appeals are an integral part of the appraisal process.
- If no appeal is lodged then the FAD becomes the Institute's final guidance and is issued to the NHS in England and Wales.
- If an appeal is lodged then an independent Appeal Panel considers the appeal(s) and in line with the Institute's published policies NICE informs appellants and stakeholders of the outcome of the appeal as soon as practicably possible. The Panel consists of five members

drawn from the Institute’s Appeals Committee (all of whom have not previously been involved in the appraisal).

- Appeals can be either upheld or rejected. If an appeal is upheld, the Appraisal Committee is asked to revisit the evidence and reconsider the FAD in the light of the Appeal Panel's findings. If an appeal is rejected the FAD becomes guidance and is issued to the NHS in England and Wales.

There are five documents that describe the process that the Institute uses to undertake technology appraisals and provide guidance to the organisations invited to contribute to these appraisals. The five documents in the Technology Appraisals Process series are:

1. Guide to the Technology Appraisal Process
2. Guidance for Appellants
3. Guidance for Patient/Carer Groups
4. Guidance for Healthcare Professional Groups
5. Technical Guidance for Manufacturers and Sponsors.

Appendix G gives details of how to order copies of these guides and copies of NICE guidance (including patient versions of guidance). You can also download copies of the guides and guidance from the NICE website (www.nice.org.uk).

Appendix F: Clinical Guidelines Development Process – Summary

1. The Institute has been asked by the Department of Health in England and the Welsh Assembly Government to develop and publish clinical guidelines for the NHS based on evidence of both clinical and cost effectiveness. As with technology appraisals the Department of Health and the Welsh Assembly Government select the topics for the Institute's Clinical Guidelines work programme.
2. The Institute will produce around 20 clinical guidelines per year.
3. Seven National Collaborating Centres (NCCs) have been established by the Institute to develop clinical guidelines on its behalf. Each Collaborating Centre is a professionally led group that has the expertise and experience necessary to support the development of clinical guidelines (the NCCs are listed in Appendix C).
4. Organisations whose interest is within the scope of the guideline will be invited to be stakeholders in that guideline and involved in the development process as follows.

New Programmes
The opportunities for stakeholder involvement in the guidelines the Institute commissions will be at points throughout the process, these points are summarised below.

Initiation

CALL FOR EXPRESSIONS OF INTEREST

Each time a new programme is announced, the Institute will call for expressions of interest from stakeholders. Information on the work programme and how to register as a stakeholder will be posted on the Institute's website. In addition the Institute will issue a press release and contact organisations that have previously registered and who may have an interest in a related guideline.

To express an interest, organisations will complete a Stakeholder Interest Form, which can be accessed from the

Institute's web site. If an organisation does not have access to the Internet, they can write to the Institute marking their letter or fax for the attention of GUIDELINES, requesting a copy of the Stakeholder Interest Form. The Institute will respond to potential stakeholders within 28 days of receipt of the form.

Stakeholders are typically the national organisations that represent patients and carers, those that represent health professionals and also individual commercial companies working in the area covered by the scope of the guideline. Stakeholders bring their own perspective to the clinical area that is being addressed by the guideline.

SCOPE CONSULTATION

During the scoping process the NCC will propose:

- The patient groups that will be considered in the guideline
- The healthcare setting for the guideline (for example, the guideline may focus on general practice or perhaps on maternity care in hospital)
- The range of treatments and/or approaches to management that will be assessed in the development of the guideline
- How the Centre will assess the clinical and cost effectiveness of the treatments and management approaches that are considered

These are presented in the consultation draft of the scope, which is circulated by the Institute to stakeholders with an invitation to comment. The Guidelines Review Panels also comment on the draft scope.

The comments are collated and a second draft of the scope is prepared. The Guidelines Review Panel then checks that the second draft of the scope meets the remit, and that stakeholders' comments have been considered fairly. The final scope is then produced.

Work plan

The NCC submits a workplan for developing the guideline, based on the scoping document. Once the workplan has been agreed by the Institute, the final scope and timetable are posted on the Institute's website. The 'scope consultation table', which summarises the comments received on the consultation draft of the scope and the Institute's response, is also posted on the Institute's website.

Development

GUIDELINES DEVELOPMENT GROUP

The development of the guideline is the responsibility of the NCC to which it has been allocated by the Institute. For each guideline the NCC establishes a Guideline Development Group (GDG). This group, consisting of representatives from key patient/carer organisations, as well as professional stakeholder organisations, carries out the main developmental work, which includes assessing the evidence available on the condition and treatments, and translating it into recommendations for practice. Regular progress reports are provided by the NCC for the Institute and the Guidelines Review Panel, and information on the progress of each guideline is made available on the Institute's website.

SUBMISSION OF EVIDENCE

The GDG will base its recommendations on a systematic review of the evidence, which it will wish to supplement with one or more of the following:

- patient, user and carer perception of the condition and its management
- unpublished clinical studies or economic modelling
    - health professional perception of the condition and its management

All stakeholders will be approached by the GDG to establish whether they wish to submit evidence falling into any of these categories and if so, the nature of this evidence. Original evidence that falls within the scope of the guideline and meets the methodological criteria will be accepted. Stakeholders will be given two months to prepare and submit the evidence that is called for.

Evidence submitted to the GDG will not be made public in the form it is received. Data and other evidence used by the Group in the preparation of the guideline will be made public, in the guideline itself and in the evidence base, at the second consultation stage and when the guideline is published. The Institute would prefer not to receive data submitted as 'commercial in confidence' because, if it is used, it will compromise the publication of the evidence base. However, where a stakeholder indicates it has such data and the Guideline Development Group wishes to use it, this data will only be seen by members of the Guideline Development Group.

Validation

CONSULTATION ON FINAL DRAFTS

The NCC will send the first draft version of the full guideline and short-form guideline to the Institute, which circulates it to all stakeholders and the Guidelines Review Panel. Stakeholders will have four weeks to return their comments. The GDG will consider and log all comments and respond. This log will be sent, along with the formal methodological appraisal, to the Guidelines Review Panel for review.

The GDG incorporates the comments received on the first draft versions to produce a second set of draft documents (including the information for the public) which are sent to stakeholders and posted on the Institute's website. The period of consultation will again be four weeks. The comments from stakeholders, and the responses to them from the GDG, are also summarised in a consultation table and published on the NICE website.

PUBLICATION

Once comments have been considered a third and final draft is produced for sign-off by the GDG, the Guidelines Review Panel and the Institute. The Institute will publish both the short-form version and the information for the public and distribute these appropriately throughout the NHS. In addition the short-form version, the information for the public and the full guideline will be available on the Institute's website.

Full details of the process are published on the Institute's web site www.nice.org.uk.

Appendix G: Interventional Procedures Process – Summary

1. NICE makes recommendations about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use. An interventional procedure is a procedure used for diagnosis or treatment that involves one of the following:
    - Making a cut or a hole to gain access to the inside of a patient's body – for example, when carrying out an operation or inserting a tube into a blood vessel
    - Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body – for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth
    - Using electromagnetic energy (which includes X-rays, lasers, gamma-rays and ultraviolet light) or ultrasound – for example, using a laser to treat eye problems.
2. By reviewing evidence, facilitating data collection and analysis, and providing guidance on the safety and efficacy of interventions, the interventional procedures programme enables clinical innovation to be responsibly managed. Many of the procedures that the programme investigates are new, but the programme also scrutinises more established procedures if there is uncertainty about safety or efficacy.
3. NHS healthcare professionals are responsible for notifying procedures to NICE and applying the guidance to meet the needs of individual patients. Although procedures are most commonly notified by clinicians, any individual or organisation may notify procedures that are being performed or are likely to be performed within the NHS.
4. The interim process that the Institute follows for interventional procedures is published on the NICE website (www.nice.org.uk). The full process will be issued for a 3 month consultation in early 2004. In summary:
    - The guidance development process begins when a

procedure has been notified to NICE by a clinician, or by another individual or organisation.

- Once notified, NICE prepares an 'Overview' of the procedure, including a brief, non-comprehensive literature search and consults at least three Specialist Advisors nominated by healthcare professional bodies
- The independent Interventional Procedures Advisory Committee (IPAC) then considers the procedure, and decides either to produce guidance, or that more information is needed before guidance can be produced.

a) If no further information is needed – guidance is produced:

- IPAC produces a consultation document that is published on the NICE website for a four week consultation period. Individuals and organisations that have expressed an interest in the procedure are informed when consultation begins and can submit comments via the NICE web site, email or by post.
- IPAC reviews the consultation document in the light of comments received following consultation, and produces a final document containing recommendations for the procedure. The NICE Guidance Executive receives and considers final recommendations from the committee on behalf of the NICE Board. NICE then issues guidance to the NHS in England and Wales.

b) If the Committee decides that more information is needed:

- The procedure is referred to an independent Review Body made up of a consortium of three universities and a teaching hospital NHS Trust.
- In addition, the Committee produces a consultation document that is published on the NICE website for a four week consultation period.
- The Review Body produces a systematic review and, if appropriate, organises data collection in collaboration with the relevant specialist societies, Royal Colleges or other professional organisations. When sufficient data is available the Review Body prepares an evaluation report.
- The committee considers this evaluation report along with

submissions from key stakeholders: this includes patient/carer organisations, professional bodies and manufacturers. The committee will then produce an updated consultation document.

- This second consultation document is published on the NICE website, again for a four-week consultation period. Individuals and organisations that have expressed an interest in the procedure under consultation will be informed when consultation begins and can submit comments via the NICE web site or by post.
- IPAC reviews the second consultation document in the light of comments received during the consultation process, and produces a final document containing recommendations for the procedure. The NICE Guidance Executive receives and considers final recommendations from the committee on behalf of the NICE Board. NICE then issues guidance to the NHS in England and Wales.

Appendix H: Ordering information

To order further copies of NICE publications telephone the NHS Response Line on 0870 1555 455 and quote the relevant reference number given below. Alternatively the documents can be downloaded from the NICE website at www.nice.org.uk.

CLINICAL GUIDELINES

*CG7 Pressure ulcer prevention – Pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care**

Short form	Ref: N0330
English version for the public	Ref: N0331
Welsh and English version for the public	Ref: N0332

* Incorporates the recommendations in *Inherited Clinical Guideline* B published by the Institute in April 2001

The recommendations in this document are derived from two guidelines. The guideline on pressure ulcer risk assessment and prevention was a part of the Institute's inherited clinical guidelines work programme. It was commissioned by the Department of Health from the Royal College of Nursing. The full guideline, *Pressure Ulcer Risk Assessment and Prevention*, is available on the NICE website (www.nice.org.uk). The National Institute for Clinical Excellence commissioned the development of the guidance on pressure-relieving devices from the National Collaborating Centre for Nursing and Supportive Care. The full guideline, *Clinical Practice Guideline for Pressure-relieving Devices: the Use of Pressure-relieving Devices (Beds, Mattresses and Overlays) for the Prevention of Pressure Ulcers in Primary and Secondary Care*, is published by the National Collaborating Centre for Nursing and Supportive Care; it is available on the NICE website (www.nice.org.uk) and on the website of the National Electronic Library for Health (www.nelh.nhs.uk).

CG6 Antenatal care: routine care for the healthy pregnant woman

Short form	Ref: N0309
English version for the public	Ref: N0310
Welsh and English version for the public	Ref: N0311

The National Institute for Clinical Excellence commissioned the development of this guidance from the National Collaborating Centre for Women and Children's Health. The full guideline, *Antenatal Care: Routine Care for the Healthy Pregnant Woman*, is published by the National Collaborating Centre for Women and Children's Health; it is available on its website (www.rcog.org.uk), the NICE website (www.nice.org.uk) and on the website of the National Electronic Library for Health (www.nelh.nhs.uk).

CG5 Chronic heart failure – Management of chronic heart failure in adults in primary and secondary care

Short form	Ref: N0247
English version for the public	Ref: N0248
Welsh and English version for the public	Ref: N0249

The National Institute for Clinical Excellence commissioned the development of this guidance from the National Collaborating Centre for Chronic Conditions. The full guideline, *Chronic Heart Failure: Management of Chronic Heart Failure in Adults in Primary and Secondary Care*, is published by the National Collaborating Centre for Chronic Conditions; it is available on its website (www.rcplondon.ac.uk/college/ceeu/ncccc_index.htm), the NICE website (www.nice.org.uk) and on the website of the National Electronic Library for Health (www.nelh.nhs.uk).

CG4 Triage, assessment, investigation and early management of head injury in infants, children and adults

Short form	Ref: N0234
English version for the public	Ref: N0235
Welsh and English version for the public	Ref: N0236

The National Institute for Clinical Excellence commissioned the development of this guidance from the National Collaborating Centre for Acute Care. The full guideline, *Head Injury: Triage, Assessment, Investigation and Early Management in Infants, Children and Adults* is published by the National Collaborating Centre for Acute Care; it is available on the NICE website (www.nice.org.uk) and on the website of the National Electronic Library for Health (www.nelh.nhs.uk).

CG3 Routine preoperative tests for elective surgery

Short form	Ref: N0231
English version for the public	Ref: N0232
Welsh and English version for the public	Ref: N0233

The National Institute for Clinical Excellence commissioned the development of this guidance from the National Collaborating Centre for Acute Care. The full guideline, *Preoperative tests. The use of routine preoperative tests for elective surgery. Evidence, methods and guidance*, is published by the National Collaborating Centre for Acute Care; it is available on the NICE website (www.nice.org.uk) and on the website of the National Electronic Library for Health (www.nelh.nhs.uk).

CG2 Infection control – Prevention of healthcare-associated infection in primary and community care

Short form	Ref: N0218
English version for the public	Ref: N0219
Welsh and English version for the public	Ref: N0220

The National Institute for Clinical Excellence commissioned the development of this guidance from Thames Valley University under the auspices of the National Collaborating Centre for Nursing and Supportive Care. The full guideline, *Infection control: guidelines for preventing healthcare-associated infections in primary and community care*, is published by Thames Valley University, it is available on its website (www.richardwellsresearch.com), the NICE website (www.nice.org.uk), and on the website of the National Electronic Library for Health (www.nelh.nhs.uk).

CG1 – Schizophrenia: Core interventions in the treatment and management of schizophrenia in primary and secondary care

Full guidance	Ref: N0176
English version for the public	Ref: N0177
English and Welsh version for the public	Ref: N0178

The National Institute for Clinical Excellence commissioned the development of this guidance from the National Collaborating Centre for Mental Health. The full guideline, *Schizophrenia: Core Interventions in the Treatment and Management of Schizophrenia in Primary and Secondary Care*, has been published by the National Collaborating Centre for Mental

Health; it will be available from its website, the NICE website (www.nice.org.uk) and the website of the National Electronic Library for Health (www.nelh.nhs.uk).

Inherited Clinical Guideline H – Management of Type 2 diabetes: Management of blood pressure and blood lipids

Short form	Ref: N0167
English version for the public	Ref: N0168
English and Welsh version for the public	Ref: N0169

The full guidelines entitled *Clinical Guidelines for Type 2 Diabetes: Blood Pressure Management* and *Clinical Guidelines for Type 2 Diabetes: Lipids Management* were commissioned by the Department of Health from the Royal College of General Practitioners, the Royal College of Physicians, the Royal College of Nursing and Diabetes UK. This is one of a series of guidelines on type 2 diabetes. It is available from the Institute's website (www.nice.org.uk) and the National Electronic Library for Health's website (www.nelh.nhs.uk).

Inherited Clinical Guideline G – Management of Type 2 diabetes: Management of blood glucose

Short form	Ref: N0128
English version for the public	Ref: N0129
English and Welsh version for the public	Ref: N0130

The full guidelines entitled *Clinical Guidelines for Type 2 Diabetes: Management of Blood Glucose* was commissioned by the Department of Health from the Royal College of General Practitioners, the Royal College of Physicians, the Royal College of Nursing and Diabetes UK. This is one of a series of guidelines on type 2 diabetes. It is available from the Institute's website (www.nice.org.uk) and the National Electronic Library for Health's website (www.nelh.nhs.uk).

Inherited Clinical Guideline F – Management of type 2 diabetes: Renal disease prevention and early management

Full guidance	Ref: N0061
English version for the public	Ref: N0062
English and Welsh version for the public	Ref: N0063

The full guideline entitled *Diabetic Renal Disease: Prevention and Early Management* was commissioned by the Department of Health from the Royal College of General Practitioners, the

Royal College of Physicians, the Royal College of Nursing and Diabetes UK. This is one of a series of inherted guidelines on type 2 diabetes. It is available from the Institute's website (www.nice.org.uk) and the National Electronic Library for Health's website (www.nelh.nhs.uk).

Inherited Clinical Guideline E – Management of type 2 diabetes: Retinopathy screening and early management

Full guidance	Ref: N0058
English version for the public	Ref: N0059
English and Welsh version for the public	Ref: N0060

The full guideline entitled *Diabetic Retinopathy: Early Management and Screening* was commissioned by the Department of Health from the Royal College of General Practitioners, the Royal College of Physicians, the Royal College of Nursing and Diabetes UK. This is one of a series of inherted guidelines on type 2 diabetes. It is available from the Institute's website (www.nice.org.uk), and the National Electronic Library for Health's website (www.nelh.nhs.uk).

Inherited Clinical Guideline D – Induction of labour

Full guidance	Ref: 24010
English version for the public	Ref: 24011
English and Welsh version for the public	Ref: 24012

The full guideline entitled *Induction of labour* was commissioned by the Department of Health from the Royal College of Obstetricians and Gynaecologists. It is available from the Institute's website (www.nice.org.uk), the National Electronic Library for Health's website (www.nelh.nhs.uk), and the RCOG's website at www.rcog.org.uk.

Inherited Clinical Guideline C – The use of electronic fetal monitoring

Full guidance	Ref: 23807
English version for the public	Ref: 23809
Bi-lingual patient version	Ref: 23810

The full guideline entitled *The use of electronic fetal monitoring* was commissioned by the Department of Health from the Royal College of Obstetricians and Gynaecologists. It is available from the Institute's website (www.nice.org.uk), the

National Electronic Library for Health's website (www.nelh.nhs.uk), and the RCOG's website at www.rcog.org.uk.

Inherited Clinical Guideline B – Pressure ulcer risk management and prevention
See Clinical Guideline 7, above.

Inherited Clinical Guideline A – Primary care management of secondary prophylaxis for patients who have experienced a myocardial infarction

Guideline	Ref: 23652
English version for the public	Ref: 23653
English and Welsh version for the public	Ref: 23654

The full guideline entitled *Prophylaxis for patients who have experienced a myocardial infarction: drug treatment, cardiac rehabilitation and dietary manipulation* was commissioned by the Department of Health from the Centre for Health Services Research University of Newcastle upon Tyne and the Medicines Evaluation Group, Centre for Health Economics, University of York. It is available from the Institute's website (www.nice.org.uk) and the National Electronic Library for Health's website (www.nelh.nhs.uk)

INTERVENTIONAL PROCEDURES

IPG17 Embolisation of intracranial aneurysms

Full guidance	Ref: N0324
English Information for the public	Ref: N0325
Welsh and English information for the public	Ref: N0326

IPG16 Laparoscopic radical prostatectomy

Full guidance	Ref: N0321
English Information for the public	Ref: N0322
Welsh and English information for the public	Ref: N0323

IPG15 Transurethral needle ablation of prostate (TUNA)

Full guidance	Ref: N0318
English Information for the public	Ref: N0319
Welsh and English information for the public	Ref: N0320

IPG14 Transurethral electrovapourisation of prostate (TEVAP)

Full guidance	Ref: N0315
English Information for the public	Ref: N0316

Welsh and English information for the public	Ref: N0317
IPG13 Islet cell transplantation	
Full guidance	Ref: N0312
English Information for the public	Ref: N0313
Welsh and English information for the public	Ref: N0314
IPG12 Percutaneous vertebroplasty	
Full guidance	Ref: N0281
English Information for the public	Ref: N0282
Welsh and English information for the public	Ref: N0283
IPG11 Stereotactic radiosurgery for trigeminal neuralgia using the gamma knife	
Full guidance	Ref: N0278
English Information for the public	Ref: N0279
Welsh and English information for the public	Ref: N0280
IPG10 Stent–graft placement in abdominal aortic aneurysm	
Full guidance	Ref: N0275
English Information for the public	Ref: N0276
Welsh and English information for the public	Ref: N0277
IPG9 Coblation tonsillectomy	
Full guidance	Ref: N0272
English Information for the public	Ref: N0273
Welsh and English information for the public	Ref: N0274
IPG8 Radiofrequency ablation of varicose veins	
Full guidance	Ref: N0269
English Information for the public	Ref: N0270
Welsh and English information for the public	Ref: N0271
IPG7 Microwave endometrial ablation	
Full guidance	Ref: N0262
English Information for the public	Ref: N0263
Welsh and English information for the public	Ref: N0264
IPG6 Balloon thermal endometrial ablation	
Full guidance	Ref: N0256
English Information for the public	Ref: N0257
Welsh and English information for the public	Ref: N0258
IPG5 Sacral nerve stimulation for faecal incontinence	
Full guidance	Ref: N0253

English Information for the public	Ref: N0254
Welsh and English information for the public	Ref: N0255

IPG4 Sacral nerve stimulation for urge incontinence

Full guidance	Ref: N0250
English Information for the public	Ref: N0251
Welsh and English information for the public	Ref: N0252

IPG3 Minimally invasive placement of pectus bar

Full guidance	Ref: N0244
English Information for the public	Ref: N0245
Welsh and English information for the public	Ref: N0246

IPG2 Radiofrequency ablation of hepatocellular carcinoma

Full guidance	Ref: N0241
English Information for the public	Ref: N0242
Welsh and English information for the public	Ref: N0243

IPG1 Uterine artery embolisation for fibroids

Full guidance	Ref: N0238
English Information for the public	Ref: N0239
Welsh and English information for the public	Ref: N0240

TECHNOLOGY APPRAISALS

NOTE

Health Technology Assessment (HTA) reports on which the technology appraisals are based are only available from the website.

No 68 – Photodynamic therapy for age-related macular degeneration

Full guideline	Ref: N0303
Bi-lingual summary	Ref: N0304
English patient version	Ref: N0305
Welsh and English patient version	Ref: N0306

No 67 – Oseltamivir and amantadine for the prophylaxis of influenza

Full guideline	Ref: N0292
Bi-lingual summary	Ref: N0293
English patient version	Ref: N0294
Welsh and English patient version	Ref: N0295

No 66 – Olanzapine and valproate semisodium in the treatment of acute mania associated with bipolar I

Full guideline	Ref: N0288
Bi-lingual summary	Ref: N0289
English patient version	Ref: N0290
Welsh and English patient version	Ref: N0291

No 65 – Rituximab for aggressive non Hodgkin's Lymphoma

Full guideline	Ref: N0284
Bi-lingual summary	Ref: N0285
English and English patient version	Ref: N0286
Welsh and English patient version	Ref: N0287

No 64 – Human growth hormone (somatropin) in adults with growth hormone deficiency

Full guideline	Ref: N0265
Bi-lingual summary	Ref: N0266
English patient version	Ref: N0267
Welsh and English patient version	Ref: N0268

No 63 – Glitazones for the treatment of type 2 diabetes
(This guidance replaces Technology guidance No. 9, published in August 2000, and No. 21, published in March 2001)

Full guideline	Ref: N0209
Bi-lingual summary	Ref: N0210
English patient version	Ref: N0211
Welsh and English patient version	Ref: N0212

No 62 – Capecitabine for the treatment of locally advanced or metastatic breast cancer

Full guideline	Ref: N0226
Bi-lingual summary	Ref: N0227
English patient version	Ref: N0228
Welsh and English patient version	Ref: N0229

No 61 – Capecitabine and tegafur with uracil for metastatic colorectal cancer

Full guideline	Ref: N0221
Bi-lingual summary	Ref: N0222
English patient version	Ref: N0223
Welsh and English patient version	Ref: N0224

No 60 – Patient-education models for diabetes

Full guidance	Ref: N0213

A4 summary	Ref: N0214
English version for the public	Ref: N0215
English and Welsh version for the public	Ref: N0216

No 59 – Electroconvulsive therapy in the treatment of depressive illness, mania, schizophrenia and catatonia

Full guidance	Ref: N0205
A4 summary	Ref: N0206
English version for the public	Ref: N0207
English and Welsh version for the public	Ref: N0208

No 58 – Zanamivir, oseltamivir and amantadine for the treatment of influenza

Full guidance	Ref: N0198
A4 summary	Ref: N0199
English version for the public	Ref: N0200
English and Welsh version for the public	Ref: N0201

No 57 – Continuous subcutaneous insulin infusion for diabetes

Full guidance	Ref: N0194
A4 summary	Ref: N0195
English version for the public	Ref: N0196
English and Welsh version for the public	Ref: N0197

No 56 – Tension-free vaginal tape (Gynecare TVT) for stress incontinence

Full guidance	Ref: N0190
A4 summary	Ref: N0191
English version for the public	Ref: N0192
English and Welsh version for the public	Ref: N0193

No 55 – Paclitaxel for the treatment of ovarian cancer

Full guidance	Ref: N0185
A4 summary	Ref: N0186
English version for the public	Ref: N0187
English and Welsh version for the public	Ref: N0188

No 54 – Vinorelbine for the treatment of advanced breast cancer

Full guidance	Ref: N0140
A4 summary	Ref: N0141
English version for the public	Ref: N0142
English and Welsh version for the public	Ref: N0143

No 53 – Long-acting insulin analogues for the treatment of diabetes – insulin glargine

Full guidance	Ref: N0179
A4 summary	Ref: N0180
English version for the public	Ref: N0181
English and Welsh version for the public	Ref: N0182

No. 52 – Early thrombolysis for myocardial infarction

Full guidance	Ref: N0170
Bi-lingual summary	Ref: N0171
English patient version	Ref: N0172
Welsh patient version	Ref: N0173

No. 51 – Computerised cognitive behavioural therapy for anxiety and depression

Full guidance	Ref: N0156
Bi-lingual summary	Ref: N0157
English patient version	Ref: N0158
Welsh patient version	Ref: N0159

No. 50 – Imatinib for chronic myeloid leukaemia

Full guidance	Ref: N0150
Bi-lingual summary	Ref: N0151
English patient version	Ref: N0152
Welsh patient version	Ref: N0153

No. 49 – Ultrasound locating devices for placing central venous catheters

Full guidance	Ref: N0146
Bi-lingual summary	Ref: N0147
English patient version	Ref: N0148
Welsh patient version	Ref: N0149

No. 48 – Home compared with hospital haemodialysis for patients with end-stage renal failure

Full guidance	Ref: N0160
Bi-lingual summary	Ref: N0161
English patient version	Ref: N0162
Welsh patient version	Ref: N0163

No. 47 – Glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes – review

(This guidance replaces guidance no. 12 issued in September 2000)

Full guidance	Ref: N0131
Bi-lingual summary	Ref: N0132
English patient version	Ref: N0133
Welsh patient version	Ref: N0134

No. 46 – Surgery for people with morbid obesity

Full guidance	Ref: N0119
Bi-lingual summary	Ref: N0120
English patient version	Ref: N0121
Welsh patient version	Ref: N0122

No. 45 – Caelyx for advanced ovarian cancer

Full guidance	Ref: N0114
Bi-lingual summary	Ref: N0115
English patient version	Ref: N0116
Welsh patient version	Ref: N0117

No. 44 – Metal on metal hip resurfacing arthroplasty

Full guidance	Ref: N0102
Bi-lingual summary	Ref: N0103
English patient version	Ref: N0104
Welsh patient version	Ref: N0105

No. 43 – Newer (atypical) antipsychotic drugs for schizophrenia

Full guidance	Ref: N0106
Bi-lingual summary	Ref: N0107
English patient version	Ref: N0108
Welsh patient version	Ref: N0109

No. 42 – Human growth hormone (somatropin) for children with growth failure

Full guidance	Ref: N0095
Bi-lingual summary	Ref: N0096
English patient version	Ref: N0097
Welsh patient version	Ref: N0098

No. 41 – Anti-D prophylaxis for rhesus negative women

Full guidance	Ref: N0091
Bi-lingual summary	Ref: N0092
English patient version	Ref: N0093
Bi-lingual patient version	Ref: N0094

No. 40 – Infliximab for Crohn's disease

Full guidance	Ref: N0087

Bi-lingual summary	Ref: N0088
English patient version	Ref: N0089
Bi-lingual patient version	Ref: N0090

No. 39 – Nicotine replacement therapy (NRT) and buprobion for smoking cessation

Full guidance	Ref: N0082
Bi-lingual summary	Ref: N0083
English patient version	Ref: N0084
Bi-lingual patient version	Ref: N0085

No. 38 – Inhaler devices for the treatment of chronic asthma in older children (aged 5–15 years)

Full guidance	Ref: N0047
Bi-lingual summary	Ref: N0048
English patient version	Ref: N0049
Bi-lingual patient version	Ref: N0050

No. 37 – Rituximab for recurrent or refractory Stage III or IV follicular non-Hodgkin's lymphoma

Full guidance	Ref: N0078
Bi-lingual summary	Ref: N0079
English patient version	Ref: N0080
Bi-lingual patient version	Ref: N0081

No. 36 – Etanercept and infliximab for the treatment of rheumatoid arthritis

Full guidance	Ref: N0074
Bi-lingual summary	Ref: N0075
English patient version	Ref: N0076
Bi-lingual patient version	Ref: N0077

No. 35 – Etanercept for the treatment of juvenile idiopathic arthritis

Full guidance	Ref: N0070
Bi-lingual summary	Ref: N0071
English patient version	Ref: N0072
Bi-lingual patient version	Ref: N0073

No. 34 – Trastuzumab for the treatment of advanced breast cancer

Full guidance	Ref: N0064
Bi-lingual summary	Ref: N0065

English patient version	Ref: N0066
Bi-lingual patient version	Ref: N0067

No. 33 – Irinotecan, oxaliplatin and raltitrexed for advanced colorectal cancer

Full guidance	Ref: N0043
Bi-lingual summary	Ref: N0044
English patient version	Ref: N0045
Bi-lingual patient version	Ref: N0046

No. 32 – Beta interferon and glatiramer acetate for multiple sclerosis

Full guidance	Ref: N0051
Bi-lingual summary	Ref: N0052
English patient version	Ref: N0053
Bi-lingual patient version	Ref: N0054

No. 31 – Sibutramine for obesity in adults

Full guidance	Ref: N0033
Bi-lingual summary	Ref: N0034
English patient version	Ref: N0035
Bi-lingual patient version	Ref: N0036

No. 30 – Taxanes for breast cancer – review

(This guidance replaces Technology Guidance No. 6 published in June 2000)

Full guidance	Ref: N0029
Bi-lingual summary	Ref: N0030
English patient version	Ref: N0031
Bi-lingual patient version	Ref: N0032

No. 29 – Fludarabine for B-cell chronic lymphocytic leukaemia

Full guidance	Ref: N0025
Bi-lingual summary	Ref: N0026
English patient version	Ref: N0027
Bi-lingual patient version	Ref: N0028

No. 28 – Topetecan for advanced ovarian cancer

Full guidance	Ref: N0020
Bi-lingual summary	Ref: N0021
English patient version	Ref: N0022
Bi-lingual patient version	Ref: N0023

No. 27 – Cyclo-oxygenase (Cox) II selective inhibitors, celecoxib, refecoxib, meloxicam and etodolac for osteoarthritis and rheumatoid arthritis

Full guidance	Ref: N0016
Bi-lingual summary	Ref: N0017
English patient version	Ref: N0018
Bi-lingual patient version	Ref: N0019

No. 26 – Docetaxel, paclitaxel, gemcitabine and vinorelbine for non-small cell lung cancer

Full guidance	Ref: 24006
Bi-lingual summary	Ref: 24007
English patient version	Ref: 24008
Bi-lingual patient version	Ref: 24009

No. 25 – Gemcitabine for pancreatic cancer

Full guidance	Ref: 23811
Bi-lingual summary	Ref: 23812
English patient version	Ref: 23813
Bi-lingual patient version	Ref: 23814

No 24 – Debriding agents and specialist wound care clinics for difficult to heal surgical wounds

Full Guidance	Ref: 23723
Bi-lingual summary	Ref: 23724
English patient version	Ref: 23725
Bi-lingual patient version	Ref: 23727

No 23 – Temozolomide recurrent malignant glioma (Brain Cancer)

Full Guidance	Ref: 23698
Bi-lingual summary	Ref: 23699
English patient version	Ref: 23700
Bi-lingual patient version	Ref: 23701

No 22 – Orlistat for obesity in adults

Full guidance	Ref: 23358
Bi-lingual summary	Ref: 23363
English patient version	Ref: 23364
Bi-lingual patient version	Ref: 23365

No 21 – Pioglitazone for type 2 diabetes mellitus

See guidance No. 63.

No 20 – Riluzole (Rilutek) for motor neurone disease

Full guidance	Ref: 23071
Bi-lingual summary	Ref: 23072
English patient version	Ref: 23073
Bi-lingual patient version	Ref: 23074

No 19 – Donepezil, rivastigmine and galantamine for Alzheimer's disease

Full guidance	Ref: 23052
Bi-lingual summary	Ref: 23054
English patient version	Ref: 23053
Bi-lingual patient version	Ref: 23055

No 18 – Laparoscopic surgery for inguinal hernia

Full guidance	Ref: 22968
Bi-lingual summary	Ref: 22969
English patient version	Ref: 22970
Bi-lingual patient version	Ref: 22971

No 17 – Laparoscopic surgery for colorectal cancer

Full guidance	Ref: 22956
Bi-lingual summary	Ref: 22957
English patient version	Ref: 22958
Bi-lingual patient version	Ref: 22959

No 16 – Autologous cartilage transplantation for full thickness cartilage defects in knee joints

Full guidance	Ref: 22961
Bi-lingual summary	Ref: 22964
English patient version	Ref: 22965
Bi-lingual patient version	Ref: 22966

No 15 – Zanamivir (Relenza) for influenza

Full guidance	Ref: 22603
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Technology Appraisal Process Series

These documents describe the process the Institute uses to undertake technology appraisals and are priced £10.50 each. They are also available from the website www.nice.org.uk.

1. Guide to the Technology Appraisal Process	Ref: N0010
2. Guidance for Appellants	Ref: N0011
3. Guidance for Patient/Care Groups	Ref: N0012
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